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EVANS LAW FIRM, INC.  
INGRID EVANS (SBN 179094)  
ELLIOT WONG (SBN 285540)  
3053 Fillmore Street, #236  
San Francisco, CA 94123  
[ingrid@evanslaw.com](mailto:ingrid@evanslaw.com)  
Telephone: (415) 441-8669  
Fax: (888) 891-4906

Attorneys for Plaintiffs/Relators  
Jeff and Sherilyn Campie

## UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, ex rel.,  
STATE OF CALIFORNIA, ex rel.,  
STATE OF DELAWARE, ex rel.,  
STATE OF FLORIDA, ex rel.,  
STATE OF GEORGIA, ex rel.,  
STATE OF HAWAII, ex rel.,  
STATE OF ILLINOIS, ex rel.,  
STATE OF INDIANA, ex rel.,  
STATE OF LOUISIANA, ex rel.,  
COMMONWEALTH OF MASSACHUSETTS,  
ex rel.,  
STATE OF MICHIGAN, ex rel.,  
STATE OF MONTANA, ex rel.,  
STATE OF NEW YORK, ex rel.,  
STATE OF NEVADA, ex rel.,  
STATE OF NEW HAMPSHIRE, ex rel.,  
STATE OF NEW JERSEY, ex rel.,  
STATE OF NEW MEXICO, ex rel.,  
STATE OF OKLAHOMA, ex rel.,  
STATE OF RHODE ISLAND, ex rel.,  
STATE OF TENNESSEE, ex rel.,  
COMMONWEALTH OF VIRGINIA, ex rel.,  
STATE OF WISCONSIN, ex rel.,

Case No. CV 110941 (MEJ)

**FIRST AMENDED COMPLAINT**

FILED UNDER SEAL PURSUANT  
TO 31 U.S.C. § 3730(b)(2)

**JURY TRIAL DEMANDED**

EVANS LAW FIRM, INC.

1 NEW YORK CITY, ex rel.,  
2 CITY OF CHICAGO, ex rel., and the  
3 DISTRICT OF COLUMBIA, ex rel.,

4 JEFF CAMPIE,  
5 900 Marlin Ave.,  
6 Foster City, CA, 94404

7 and

8 SHERILYN CAMPIE,  
9 900 Marlin Ave.,  
10 Foster City, CA, 94404

11 Plaintiffs-Relators,

12 BRING THIS ACTION ON BEHALF OF THE  
13 UNITED STATES OF AMERICA; THE  
14 COMMONWEALTHS OF  
15 MASSACHUSETTS AND VIRGINIA;  
16 AND THE STATES OF CALIFORNIA,  
17 DELAWARE, FLORIDA, GEORGIA,  
18 HAWAII, ILLINOIS, INDIANA, LOUISIANA,  
19 MICHIGAN, MONTANA, NEW JERSEY,  
20 NEW YORK, NEVADA, NEW HAMPSHIRE,  
21 NEW MEXICO, NORTH CAROLINA,  
22 OKLAHOMA, RHODE ISLAND, TENNESSE,  
23 WISCONSIN; AND THE CITIES OF NEW  
24 YORK AND CHICAGO; AND THE  
25 DISTRICT OF COLUMBIA

26 ATTORNEY GENERAL OF  
27 THE UNITED STATES  
28 U.S. Department of Justice  
10th and Constitution Avenues, N.W.  
Washington, DC 20530

ATTORNEY GENERAL FOR THE  
COMMONWEALTH OF  
MASSACHUSETTS  
One Ashburton Place  
Boston, MA 02108

EVANS LAW FIRM, INC.

EVANS LAW FIRM, INC.

1 ATTORNEY GENERAL FOR THE STATE  
2 OF CALIFORNIA

3 1300 I Street  
4 P.O. Box 944255  
5 Sacramento, CA 94244-2550

6 ATTORNEY GENERAL FOR THE STATE  
7 OF DELAWARE

8 Carvel State Office Building  
9 820 N. French Street  
10 Wilmington, DE 19801

11 ATTORNEY GENERAL FOR THE STATE  
12 OF FLORIDA

13 State of Florida  
14 The Capitol  
15 PL-OI  
16 Tallahassee, FL 32399-1050

17 ATTORNEY GENERAL FOR THE STATE  
18 OF GEORGIA

19 Office of the Attorney General  
20 40 Capitol Square, SW  
21 Atlanta, GA 30334

22 ATTORNEY GENERAL FOR THE STATE  
23 OF HAWAII

24 425 Queen Street  
25 Honolulu, HI 96813

26 ATTORNEY GENERAL FOR THE STATE  
27 OF ILLINOIS

28 100 West Randolph Street  
Chicago, IL 60601

ATTORNEY GENERAL FOR THE STATE  
OF INDIANA

Indiana Government Center South  
302 W. Washington Street  
Indianapolis, IN 46204

1 ATTORNEY GENERAL FOR THE STATE  
2 OF LOUISIANA

3 1885 N. Third Street  
4 Baton Rouge, LA 70802

5 ATTORNEY GENERAL FOR THE  
6 STATE OF MICHIGAN

7 P.O. Box 30212  
8 525 W. Ottawa St.  
9 Lansing, MI 48933-1067

10 ATTORNEY GENERAL FOR THE  
11 STATE OF MONTANA

12 P.O. Box 201401  
13 Helena, MT 59620-1401

14 ATTORNEY GENERAL FOR THE  
15 STATE OF NEW YORK

16 Office of the Attorney General  
17 The Capitol  
18 Albany, NY 12224-0341

19 ATTORNEY GENERAL FOR THE  
20 STATE OF NEVADA

21 Carson City Office  
22 100 North Carson Street  
23 Carson City, Nevada 89701-4717

24 ATTORNEY GENERAL FOR THE  
25 STATE OF NEW HAMPSHIRE

26 Medicaid Healthcare Fraud Unit  
27 33 Capitol Street  
28 Concord, NH 03301

ATTORNEY GENERAL FOR THE STATE  
OF NEW JERSEY

Richard J. Hughes Justice Complex  
8th Floor, West Wing  
25 Market Street  
Trenton, NJ 08625-0080

ATTORNEY GENERAL FOR THE

EVANS LAW FIRM, INC.

1 STATE OF NEW MEXICO  
2 P.O. Box 1508  
3 Santa Fe, NM 87504-1508

4 ATTORNEY GENERAL FOR THE  
5 STATE OF OKLAHOMA  
6 313 NE 21st Street  
7 Oklahoma City, OK 73105

8 ATTORNEY GENERAL FOR THE STATE  
9 OF RHODE ISLAND  
10 150 South Main Street  
11 Providence, RI 02903

12 ATTORNEY GENERAL FOR THE  
13 STATE OF TENNESSEE  
14 P.O. Box 20207  
15 Nashville, IN 37202-4015

16 ATTORNEY GENERAL FOR THE  
17 COMMONWEALTH OF VIRGINIA  
18 Office of the Attorney General  
19 900 East Main Street  
20 Richmond, Virginia 23219

21 ATTORNEY GENERAL FOR THE STATE  
22 OF WISCONSIN  
23 114 East State Capitol  
24 Madison, WI 53707-7857

25 NEW YORK CITY  
26 Department of Investigation,  
27 80 Maiden Lane, New York, New York 10038

28 CITY OF CHICAGO  
OFFICE OF THE CLERK OF THE CITY  
121 N. La Salle Street  
Chicago, IL 60602, and

ATTORNEY GENERAL FOR THE  
DISTRICT OF COLUMBIA  
441 4th Street NW, Suite 1060 N

1 Washington, DC 20001

2  
3 v.

4 GILEAD SCIENCES, INC.  
5 333 Lakeside Drive, Foster City, CA 94404.

6 GILEAD SCIENCES ULC  
7 1021 Hayter Road  
8 Edmonton, Alberta

9 Defendants.

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EVANS LAW FIRM, INC.

**AMENDED COMPLAINT**

Plaintiff-Relators, Jeff and Sherilyn Campie, in the name of and on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Mexico, the State of New York, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, and the State of Wisconsin, and the City of Chicago, the City of New York, and the District of Columbia, by their attorneys, Evans Law Firm, Inc., as and for their complaint, allege as follows:

**INTRODUCTION**

1. As more fully alleged herein, this action arises out of a scheme or schemes to defraud the United States of America, the fifty states, and the District of Columbia perpetrated by defendants Gilead Sciences, Inc. ("Gilead") and Gilead Alberta LLC (aka Gilead Alberta), commencing in or before 2001 and continuing to the date hereof. The defendants made and/or caused to be made to the United States, the fifty state governments, the city of Chicago, New York City, and the District of Columbia false claims for payment for prescription drugs covered by Medicare, state Medicaid programs, the Department of Veterans Affairs, the public health service and other federal, state and city purchasers of prescription drugs. The claims were false and fraudulent because the drugs, which were manufactured at defendant's plants in various locations, both inside

1 and outside the United States, and released into the domestic and foreign commercial and  
2 clinical marketplaces by Gilead, were defective, not manufactured in accordance with  
3 Food and Drug Administration ("FDA") approved processes, and/or did not come with  
4 the assurance of identity, strength, quality and purity required for distribution to patients;  
5 and/or approvals for the drugs were obtained through false representations in regulatory  
6 submissions to the FDA. The false claims arose out of chronic, serious deficiencies in the  
7 Quality Assurance functions at the defendants' plants and the defendants' ongoing serious  
8 violations of the laws and regulations designed to ensure the fitness of drug products for  
9 use, including the federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 et seq., and  
10 the Code of Federal Regulations, Title 21.

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14 2. The drugs affected by the defendant's conduct include Gilead drug products Viread,  
15 Truvada, Hepsera, Emtriva, Atripla, Letairis, Cayston, Macugen, Complera, and Stribild,  
16 and multiple Gilead clinical trial drugs in various phases of the FDA application approval  
17 process.

18  
19 3. Examples of defective and/or misidentified products that Gilead released, and Gilead  
20 Alberta caused to be released, to the United States market are:

21  
22 A. Drugs for the treatment of hiv/aids that were:

- 23 (i) Manufactured at unregistered foreign facilities;  
24  
25 (ii) Tainted with visible filth, metal content, foreign ingredients, microbial  
26 contamination, and other undisclosed adulterations and contaminations; and  
27  
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1 (iii) Maintained, stored, and shipped without the controls necessary to ensure  
2 compliance with the labeled, approved environmental conditions, including at extreme,  
3 uncontrolled and undocumented temperatures, resulting in accelerated impurities, and  
4 broken, moist, melted, and/or fused drug products;  
5

6 B. An inhaled drug for the treatment of Cystic fibrosis (cf) known to contain iron and  
7 cadmium metal particulates;  
8

9 C. A treatment for macular (eye) degeneration known to consist of contaminated sterile  
10 drug product accompanied by complaints of dull and bent needles.  
11

12 D. Drug product lots confirmed to be mixed up in the same bottle with drug product of  
13 a different type or strength;  
14

15 E. Clinical trial drugs, including drugs subsequently approved for sale, for the  
16 treatment of HIV/AIDS, including in the pediatric population, containing black particles,  
17 foreign matter, gross contamination, and visible filth;  
18

19 F. A comparator drug used in a late-phase clinical study for the treatment of Hepatitis  
20 C that was injected in test patients despite being subjected to extreme temperatures for  
21 days prior to use and deemed by the company as "unusable"; and  
22

23 G. A "sterile" injectable drug used in a late-phase study for the treatment of chronic  
24 angina provided to patients despite containing visible foreign matter.  
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- 1 4. These acts constitute violations of the federal false claims act, 31 U.S.C. § 3729, et. Seq.  
 2 ("FCA"), and numerous equivalent state statutes and city ordinances.<sup>1</sup> the FCA provides,  
 3 *inter alia*, that any person who knowingly presents and/or causes to be presented to the  
 4 United States a false or fraudulent claim for payment is liable for a civil penalty of up to  
 5 \$11,000 for each claim, plus three times the amount of the damages sustained by the  
 6 government. The FCA allows any person discovering a fraud perpetrated against the  
 7 government to bring an action for himself and for the government and to share in any  
 8 recovery. The complaint in an FCA action is filed under seal for 60 days or longer  
 9 subject to court approval (without service on the defendant(s) within such 60-day or  
 10 longer period) to enable the government (1) to conduct its own investigation without the  
 11 defendant's knowledge and (2) to determine whether to join in the action.  
 12  
 13  
 14  
 15 5. Plaintiff-Relator Jeff Campie is a former Senior Director of Global Quality Assurance for  
 16 defendant Gilead. Mr. Campie is an expert in the Code of Federal Regulations, Title 21  
 17 compliance and an experienced pharmaceutical professional with over 25 years of  
 18 experience in compliance and quality within the pharmaceutical industry. He is an expert  
 19  
 20

21 <sup>1</sup>As set forth below, the Defendants' acts constitute violations of the California False Claims Act, Cal. Gov't Code §§ 12650-12655; the  
 22 Delaware False Claims and Reporting Act, 6 Del. C. §§ 1201 et seq.; the District of Columbia Procurement Reform Amendment Act, D.C.  
 23 Code Ann. §§ 2-308.13-21; the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081-092; the Georgia State False Medicaid Claims Act,  
 24 Ga. Code Ann. §§ 49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21-29; the Illinois Whistleblower Reward and  
 25 Protection Act, 740 Ill. Comp. Stat. §§ 175/1-8; the Indiana False Claims and Whistleblower Protection Act, IC 5-115.5 et seq.; the  
 26 Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46:437.1-14; the Massachusetts False Claims Act, Mass. Gen. L. Ch.  
 27 12, §§ 5B et seq.; the Michigan Medicaid False Claims Act, MCL §§ 400.601 et seq.; the Nevada False Claims Act, Nev. Rev. Stat.  
 28 §§ 357.010 et seq.; the New Hampshire Medicaid Fraud and False Claims Act, RSA §§ 167.58 et seq.; the New Mexico Medicaid False  
 Claims Act, N.M. Stat. Ann. §§ 27-12-1 et seq.; the New York False Claims Act, N.Y. State Fin. Law §§ 187-194; the Tennessee Medicaid  
 False Claims Act, Tenn. Code Ann. §§ 71-5-182 et seq.; the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 et seq.; the Texas  
 Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann.  
 §§ 8.01-216.3 et seq.; the Chicago False Claims Act, Chicago Municipal Code Ch. 1-21 et seq.; and the New York City False Claims Act,  
 Local Law 53 of 2005, Title 7, New York City Admin. Code §§ 7-801 et seq.

1 on the technical, legal, regulatory and compliance aspects of the pharmaceutical Good  
2 Manufacturing Practices ("GMP's") and quality systems regulations relating to the  
3 development, manufacture, packaging, testing, holding and distribution of drug products,  
4 and has presented and published quality system-related materials in both the United  
5 States and the European Union. He has performed numerous domestic and foreign  
6 compliance inspections and has led successful FDA pre-approval and biennial readiness  
7 inspection programs for numerous multi-national pharmaceutical companies. Mr.  
8 Campie worked for Gilead from 2006 through mid-2009 before his employment was  
9 terminated as a result of raising objections to Gilead's conduct, as described below.  
10 During his employment at Gilead, the group headed by Mr. Campie was responsible for  
11 global quality assurance oversight of: (i) virtually all commercially-released United  
12 States and PEPFAR-based Gilead drug products; (ii) policies, practices and GMP  
13 compliance associated with Gilead's contract manufacturing organizations ("CMOs")  
14 supplying the U.S. market; and (iii) for a portion of his employment, the development of  
15 quality systems within Gilead.  
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- 20 6. Plaintiff-Relator Sherilyn Campie has a Master's Degree in Biomedical Chemistry and  
21 has been employed as a chemist for over 16 years in the pharmaceutical industry. Ms.  
22 Campie commenced full time employment with Gilead in March 2007 as a Senior  
23 Research Associate. She continues to be employed by Gilead in the role of Associate  
24 Manager, Quality Control, where she oversees the stability program for drug substance  
25 and drug product in development in clinical phase trials.  
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- 1 7. The Relators seek to recover damages and civil penalties in the name of the United States  
 2 and the states for the violations alleged herein. On information and belief, as set forth  
 3 below, the damages and civil penalties that may be assessed against the defendants under  
 4 the facts alleged in this complaint amount to at least hundreds of millions of dollars. In  
 5 addition, Relator Jeff Campie brings related claims against defendant Gilead for  
 6 retaliation arising from his termination of employment.  
 7

### 8 JURISDICTION AND VENUE

- 9  
 10 8. This Court has jurisdiction over this civil action pursuant to 28 U.S.C.. § 1331, 28 U.S.C..  
 11 § 1367 and 31 U.S.C.. § 3732.  
 12  
 13 9. Personal jurisdiction and venue are proper in this district pursuant to 28 U.S.C..  
 14 §§ 1391(b) and 1395(a) and 31 U.S.C.. § 3732(a), as at least one of the defendants is  
 15 found, has or had an agent or agents, has or had contacts, and transacts or transacted  
 16 business and their affairs in this judicial district.  
 17

### 18 PARTIES

#### 19 PLAINTIFF-RELATORS

- 20 10. Plaintiff-Relator Jeff Campie is a citizen of the United States and a resident of  
 21 California. Mr. Campie is currently a self-employed consultant with PharmaConsultUS  
 22 Inc., a New Jersey-based pharmaceutical consulting firm specializing in compliance  
 23 remediation and quality system development. Prior to June 2009, Mr. Campie had been  
 24 employed as the Senior Director of the Global Quality Assurance function within Gilead,  
 25 located in Foster City, California.  
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1 11. Plaintiff-Relator Sherilyn Campie is a citizen of the United States and a resident of  
2 California. Ms. Campie is currently an Associate Manager, Quality Control for Gilead,  
3 located in Foster City, California.  
4

#### 5 DEFENDANTS

6  
7 12. Defendant Gilead Sciences, Inc. (as defined previously, "Gilead") is headquartered at 333  
8 Lakeside Drive, Foster City, California, 94404. Gilead is a publicly-traded company  
9 engaged in the development, manufacture, promotion, sale, and interstate distribution of  
10 prescription drugs, with a focus on drug products for patients suffering from life-  
11 threatening diseases, including HIV/AIDS, Hepatitis, Cystic fibrosis and cardio-  
12 pulmonary conditions. Gilead is the world's largest producer of anti-HIV drug therapies.  
13 Gilead has 5,800 employees across five continents, with 57% of its sales of prescription  
14 drugs in the United States. In addition to using its own facilities, Gilead contracts with  
15 numerous companies for manufacture of the active pharmaceutical ingredients ("APIs")  
16 and bulk drug products comprising the pharmaceutical products that it markets and  
17 distributes. The company reported more than \$9.4 billion of revenue in 2012, over 86%  
18 of which came from the sale of its HIV/AIDS drugs Complera, Atripla, Truvada, Viread,  
19 Hepsera, and Emtriva. Due to the prohibitive cost of HIV/AIDS therapies and other life-  
20 threatening diseases treated by Gilead's drug products, and the extended duration of the  
21 therapies, the federal and state governments pay for the majority of prescriptions of  
22 Gilead drugs sold in the United States under various federal and state health care  
23 programs.  
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- 1 13. Defendant Gilead Alberta ULC ("Gilead Alberta") is headquartered at 1021 Hayter Road,  
2 Edmonton, Alberta Canada. Gilead Alberta manufactures the API's TDF, FTC,  
3 Ambrisentan, Cobicistat and Elvitegravir for use in the manufacture of Gilead drug  
4 products Letairis, Viread, Truvada, Atripla, Complera and Stribild, for both commercial  
5 sale and clinical trials. Gilead Alberta transports the API that it manufactures to various  
6 Gilead CMOs for the manufacture of finished drug products.  
7  
8 14. Defendants and the other companies referred to herein, were at all times relevant the co-  
9 conspirator, agent, employee, servant, partner, joint venture, successor, assignee,  
10 employee, ratifier, aider, and/or abettor of each Defendant with respect to the wrongful  
11 conduct alleged. Each was acting within the course and scope of said conspiracy,  
12 agency, employment, and/or joint venture and with the permission and consent of the  
13 other, and each Defendant is responsible and liable in some manner for the damages or  
14 injuries sustained or threatened to be sustained. All actions of the companies referred to  
15 herein were ratified and approved by Defendants or their officers or managing agents  
16 while acting within the course and scope of their employment.  
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#### GOVERNMENT PROGRAMS

- 20  
21 15. Medicaid is the nation's medical assistance program for the needy, the aged, blind,  
22 disabled, and families with dependent children. 42 U.S.C. §§ 1396-1396v. Medicaid is  
23 largely administered by the states and funded by a combination of federal and state funds.  
24 Approximately [57]% of medicaid funding is provided by the federal government.  
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1 Among other forms of medical assistance, the medicaid programs cover outpatient  
2 prescription drugs. 42 U.S.C. §§ 1396a(10)(a) and 1396d(a)(12).

3 16. Medicare is the nation's health program for persons over 65 and the disabled. Medicare  
4 is funded by the federal government. Medicare Part B has long covered outpatient  
5 prescription drugs that are provided to a patient "incident to" a physicians' services,  
6 including injectable medications, and drugs that are required for the effective use of  
7 durable medical equipment. 42 U.S.C. § 1395x(s)(2)(a). Commencing on January 1,  
8 2006, Medicare Part D provides comprehensive outpatient prescription drug coverage for  
9 brand name and generic drugs according to national and local coverage determinations.  
10 Medicare Prescription Drug Improvement and Modernization Act 2003, Pub. L. 108-173.  
11 All of the individual drugs identified in this complaint are covered drugs under Medicare  
12 Part D. As such, the federal and state governments are the largest end purchasers of  
13 defendants drug products identified herein.  
14

15  
16  
17 17. The Department of Veterans Affairs ("VA") provides medical assistance, including  
18 prescription drug coverage, for persons who have been discharged from active duty  
19 service in the military, naval, or air service.  
20

21 18. The Public Health Service ("PHS") provides funding, including outpatient drug coverage,  
22 for entities such as black lung clinics, AIDS drug purchasing assistance programs,  
23 hemophilia diagnostic treatment centers, urban Indian organizations, disproportionate  
24 share hospitals, and other entities listed in § 340b(a)(4) of the Public Health Service Act.  
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19. The Department of Defense ("DOD") administers the TRICARE health care program for active duty and retired members of the uniformed services, their families, and survivors. TRICARE benefits include comprehensive prescription drug coverage.
20. The Food and Drug Administration ("FDA") is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. The FDA administers, inter alia, the federal Food, Drug and Cosmetics Act, ("FDCA"), 21 U.S.C. §§ 301 et seq.

#### **ASPECTS OF THE FDA REGULATORY SCHEME**

21. The federal government endeavors to ensure the safety and efficacy of drug products consumed daily by millions of americans through a combination of approvals, inspections, enforcement, and self-regulation by drug manufacturers. As the FDA's Deputy Associate General Counsel, Eric M. Blumberg, esq., wrote, drug manufacturers "occupy a virtual fiduciary relationship to the public ... FDA shares this trustee relationship to the consumer with industry leaders, but the initial and ultimate responsibility remains with those leaders. This is true not only because the law makes it so, but also for the practical reason that the FDA cannot be in every factory, much less monitor every decision that is made every day that affects the quality of our food and drugs." Abbott Laboratories Consent Decree and Individual Responsibility Under the Federal Food Drug and Cosmetic Act, 55 Food and Drug L.J., 145, 147.

**GOOD MANUFACTURING PRACTICES**

22. Good Manufacturing Practices ("GMPs") are federal regulations that contain the minimum requirements that pharmaceutical companies must meet in manufacturing, processing, packing, warehousing, and distributing drugs to assure that they meet the safety, identity, strength, quality, and purity characteristics that they purport to possess. Pertinent GMPs are codified in 21 C.F.R. parts 210 and 211. Manufacturers demonstrate compliance with GMPs through written documentation of procedures and practices. The GMPs dictate, *inter alia*, standards for: personnel engaged in quality control; the design, construction and maintenance of buildings and facilities; the construction, cleaning and maintenance of equipment; the storage, inspection and testing of drug components and containers; the control of production and process, including procedures for sampling and testing of in-process drug products for conformity with specifications and prevention of microbiological contamination; control of packaging, labeling, storage and distribution; laboratory controls including testing of drug product batches for conformity with final specifications; the maintenance of records and reports and conduct of investigations; and procedures for handling of returned and salvaged product.
23. Drugs are deemed to be adulterated if they are not manufactured in compliance with the GMPs or if they are contaminated. See 21 U.S.C. §§ 351(a)(2)(a) and (b). It is a violation of the FDCA, 21 U.S.C. §§ 331(a) to directly or indirectly cause adulterated drugs to be introduced or delivered for introduction into interstate commerce.

**CURRENT GOOD MANUFACTURING PRACTICES**

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2  
3 24. The current Good Manufacturing Practices ("cGMP") requirements were established to  
4 allow each manufacturer to decide, individually, how to best implement the necessary  
5 controls required to be in compliance with applicable GMPs. The flexibility in the  
6 regulations is designed to promote the use of modern technologies and innovative  
7 approaches to achieve higher quality through continual improvement. Accordingly, the  
8 "c" in cGMP stands for "current", requiring companies to use technologies and systems  
9 that are up-to-date in order to comply with the regulations.  
10  
11

**ESTABLISHMENT INSPECTIONS, FDA-483S AND WARNING LETTERS**

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14 25. Under the FDCA § 704, 21 U.S.C. § 374, the FDA is authorized to conduct cGMP  
15 inspections of drug manufacturing facilities, including inspections of records, files,  
16 papers, processes, controls, and facilities. At the conclusion of the inspection, and when  
17 necessary, the FDA provides the manufacturer with a form FDA-483 ("FDA-483"), or a  
18 list of "observations" representing violations the FDA believes the manufacturer has  
19 committed. The manufacturer is expected to respond in writing to each observation  
20 stating its position and any corrective action it proposes to take. The FDA takes this  
21 response into account in deciding whether further enforcement action is warranted.  
22  
23  
24 26. Following an inspection or discovery of a violation, the FDA may issue a warning letter  
25 to the manufacturer representing its official findings of violations. FDCA § 309, 21  
26 U.S.C. § 336. The warning letter is the FDA's primary means of notifying manufacturers  
27 of serious violations and of achieving prompt corrective action. The manufacturer must  
28

1 respond in writing to the warning letter within 15 days stating what action is being taken  
2 to correct the violations, what action will be taken to prevent similar violations, and the  
3 time frame for such action.

#### 4 POST-MARKETING SURVEILLANCE

5  
6 27. The FDA operates a drug quality reporting system, which includes the Medwatch  
7 reporting program. This is designed to rapidly identify significant health hazards  
8 associated with the manufacturing and packaging of drugs, and to establish a central  
9 reporting system for detecting problem areas or trends requiring regulatory action.  
10 Doctors and pharmacists can report drug quality problems, such as defective components,  
11 poor packaging or labeling, suspected contamination or questionable stability to the FDA,  
12 the manufacturer, or both, using a standard form.

13  
14  
15 28. Pursuant to 21 C.F.R. § 314.81(b)(1)(i) & (ii), manufacturers are required to notify the  
16 FDA by filing a NDA "field alert" within three working days of learning of: (i) any  
17 incident that may cause the drug product or its labeling to be mistaken for, or applied to,  
18 another article; (ii) information concerning any bacteriological contamination, or any  
19 significant chemical, physical, or other change or deterioration in the distributed drug  
20 product, or any failure of one or more distributed batches of the drug product to meet the  
21 specifications established for it in the new drug application.  
22  
23

#### 24 PRODUCT RECALLS

25 29. The FDA expects manufacturers to take full responsibility for the recall of defective  
26 products, including follow-up efficacy checks to assure that the recalls are successful in  
27 maximizing the recovery of the defective product from the marketplace. The FDA does  
28

1 not have authority to order a mandatory recall of drug products. Under 21 C.F.R. § 7.40,  
 2 "[r]ecall is a voluntary action that takes place because manufacturers and distributors  
 3 carry out their responsibility to protect the public health and well-being from products  
 4 that present a risk of injury or gross deception or are otherwise defective." the FDA's  
 5 guidelines "categorize all recalls into one of three classes according to the level of hazard  
 6 involved: Class I recalls are for dangerous or defective products that predictably could  
 7 cause serious health problems or death. Examples of products that could fall into this  
 8 category [include] ... A label mix-up on a lifesaving drug ... Class II recalls are for  
 9 products that might cause a temporary health problem, or pose only a slight threat of a  
 10 serious nature. One example is a drug that is under-strength but that is not used to treat  
 11 life-threatening situations. Class III recalls are for products that are unlikely to cause any  
 12 adverse health reaction, but that violate FDA labeling or manufacturing regulations."  
 13 FDA Recall Policies, FDA Center for Food Safety and Applied Nutrition, Industry  
 14 Affairs Staff Brochure, June 2002. *See also* FDA Investigations Operations Manual,  
 15 Chapter 800 (801.1).

### 20 BIOEQUIVALENCE

- 21
- 22 30. The FDA has defined bioequivalence as "the absence of a significant difference in the  
 23 rate and extent to which the active ingredient or active moiety in pharmaceutical  
 24 equivalents or pharmaceutical alternatives becomes available at the site of drug action  
 25 when administered at the same molar dose under similar conditions in an appropriately  
 26 designed study. (Center for Drug Evaluation and Research (2003) Guidance for Industry:  
 27  
 28

1 Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—  
2 General Considerations.” United States Food and Drug Administration.) Due to such  
3 expectations, the manufacture of an approved drug at more than one site of manufacture  
4 involves a technology transfer process—thereby ensuring that a (pharmacological)  
5 linkage remains between commercial (drug) product and pivotal (bioequivalence)  
6 batches.  
7

### 8 VALIDATION

9  
10 31. Validation is the documented act of demonstrating that an analytical method,  
11 manufacturing process, or other regulated activity will consistently yield acceptable  
12 results. Validation is a requirement under the GMP’s to be performed prior to release of  
13 drug into interstate commerce.  
14

### 15 OVERVIEW OF GILEAD’S CLAIMS PROCESS AND GMP DEFICIENCIES

16 32. For every released batch of API or finished drug product, manufacturers are required to  
17 create a Certificate of Analysis (“COA”) certifying that the batch was manufactured  
18 according to the specifications contained either in an Investigational New Drug (“IND”)  
19 application or in a New Drug Application (“NDA”). The COA reaffirms the basis of  
20 FDA approval of the drug. By releasing the product into distribution, the manufacturer  
21 certifies compliance with applicable GMP requirements.  
22

23  
24 33. The COAs may be presented, upon demand and in filings, to state and federal  
25 governments, in clinical trials and to authorized distributors under the various  
26 government programs described above.  
27  
28

1 34. Defendants maintain an arcane, convoluted "process" for documenting batch analyses,  
2 releases, investigations, and sales. Generally speaking, the documentation process works  
3 as follows for released drug product, although the process is not adhered to rigorously,  
4 and there are many exceptions. There is also some variation when the drug is for clinical  
5 use as opposed to commercial sale.  
6

7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]

10 [REDACTED]  
11 [REDACTED]

12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]

15 [REDACTED]

16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]

20 [REDACTED]  
21 [REDACTED]

22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]

25 35. These convoluted documentation processes are vulnerable to error and manipulation. As  
26 detailed below, defendants manipulated the COA documentation process to mask known  
27  
28

1       contamination and to manufacture API at unregistered facilities without disclosing it to  
2       the government.

3       36. Defendants' chronic quality assurance problems and ongoing, serious cGMP violations go  
4       to the heart of their manufacturing, processing and packaging systems. They include  
5       and/or result in:

6  
7       A. Inadequate investigation of out-of-specification ("OOS") results detected during  
8       laboratory testing;

9  
10      B. Inadequate temperature and humidity control during storage and shipping;

11      C. Inadequate process validation and non-existent validation review processes for  
12      some products;

13  
14      D. Inadequate or non-existent calibration of equipment and instruments and  
15      incomplete investigations relating to equipment found to be out-of-calibration;

16  
17      E. Poor documentation quality, including multiple versions of a COA containing  
18      different, conflicting values for the same API or finished drug product;

19      F. Product mix-ups, i.e., a drug of a different type or strength found in the same  
20      bottle;

21      G. Contamination in products manufactured in sterile facilities;

22  
23      H. Manufacturing areas and purportedly clean equipment that repeatedly failed  
24      routine environmental testing and exhibited microbial contamination;

25  
26      I. Various other cGMP violations and quality assurance failures, including  
27      inadequate identification, control and storage of drug materials.  
28

**SUMMARY OF FALSE CLAIMS ACT LIABILITY**

37. Defendants violated the false claims act as follows:

**A. UNREGISTERED FACILITIES**

38. Defendants submitted and/or caused to be submitted false claims to the federal, state and city governments for drug products manufactured at foreign facilities before they were properly registered by the FDA. Further, during belated application for these facilities, Defendants concealed contamination issues that would have led the government to deny registration. Failure to make timely registration based upon accurate representations of a new manufacturing facility renders all sales containing product manufactured in that facility unapproved and the product misbranded under the Food Drug & Cosmetic Act. 21 C.F.R. § 314.50(d)(1)(i); 314.70(b)(2); 21 U.S.C. § 360(i) and (j). Examples of Defendants' failure to properly register foreign manufacturing facilities and to conceal contaminated product during belated registration resulting in the submission of false claims are detailed below.

**(B) DEFECTIVE PRODUCTS**

39. Defendants submitted and/or caused to be submitted false claims to the federal, state and city governments for drug products manufactured at their facilities that were defective. The defective products and false claims arose out of chronic, serious deficiencies in the quality assurance functions at the facilities and Defendants' ongoing serious violations of the laws and regulations designed to ensure the fitness of drug products for use. As a result, the government paid for an assurance of quality and fitness for use that it did not

1 receive, and all claims to the government for products manufactured by Defendants as set  
2 forth herein during the times relevant to this complaint were false. Examples of the  
3 chronic quality assurance problems and ongoing, serious cGMP violations that went to  
4 the heart of Defendants' manufacturing, processing and packaging systems, resulting in  
5 the submission of false claims are detailed below.

7 **(C) DRUG APPROVALS OBTAINED THROUGH FALSE STATEMENTS TO**  
8 **THE FDA**

9 40. Gilead obtained FDA approval for drug products containing the APIs emtricitabine  
10 ("FTC") and tenofovir disoproxil fumarate ("TDF") by making false and fraudulent  
11 statements to the FDA. In particular, Gilead obtained approval for the Gilead HIV/AIDS  
12 drug Viread in 2001, the Gilead HIV/AIDS drug products Emtriva, Emtriva Oral  
13 Solution, Truvada, and Atripla between July 2003 and July 2006, Complera in 2011, and  
14 Stribild in 2012, by falsely representing to the FDA, in each of the NDAs for these drug  
15 products, that Defendants could manufacture the drugs in a manner consistent with the  
16 NDAs, when in fact Defendants knew during the NDA processes that manufacturing of  
17 these drugs yielded various undisclosed impurities, altering the chemical makeup of the  
18 drugs. Defendants concealed from the FDA systemic quality assurance failures and  
19 significant violations of the cGMPs, including violations that Defendants were required  
20 by law to report to the FDA. As a result, all claims submitted to the government for  
21 Viread, Emtriva, Emtriva Oral Solution, Truvada, Macugen, Atripla, Complera, and  
22 Stribild during the times relevant to this complaint were false. Examples of FDA  
23  
24  
25  
26  
27  
28

1 approvals that were obtained through Gilead's false and fraudulent statements to the FDA  
2 and resulted in the submission of false claims are detailed below.

3 (i) In addition, Gilead is at various stages of the FDA approval process for new  
4 experimental and developmental drugs and formulations that are tainted by known  
5 contaminants and adulterations, which Gilead has not disclosed to the FDA even as the  
6 NDAs move through the regulatory process toward approval. The Defendants concealed  
7 from the FDA systemic quality assurance failures and significant violations of the  
8 cGMPs, including violations that the Defendants were required by law to report to the  
9 FDA. As a result, all claims submitted to the government for these developmental and  
10 experimental drugs during the times relevant to this complaint were false. Examples of  
11 FDA approvals that have been/are being sought for developmental and experimental  
12 drugs through Gilead's false and fraudulent statements to the FDA and resulted in the  
13 submission of false claims are detailed below.

14  
15  
16  
17  
18 **(D) DRUG PRODUCT NOT "COVERED" UNDER LAWS GOVERNING**  
19 **GOVERNMENT HEALTH PLANS**

20 41. For purposes of Medicare, Medicaid and other government programs, a "covered  
21 outpatient drug" is defined, *inter alia*, as one that "is approved for safety and  
22 effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug,  
23 and Cosmetic Act or which is approved under section 505(j) of such Act." See 42 U.S.C.  
24 1396r-8(k).

25  
26 (i) The intent and purpose of the FDCA and the regulatory schemes administered by  
27 the FDA are to ensure that drugs are both approved for safety and effectiveness and reach  
28

1 the market in a condition that renders them fit for their intended use. Under 21 U.S.C.  
 2 § 355(e)(5), approval of any drug may be suspended if "there is an imminent hazard to  
 3 the public health," and approval may be withdrawn following notice to the drug maker  
 4 and an opportunity to be heard if "the methods used in, or the facilities and controls used  
 5 for, the manufacture, processing, and packing of such drug are inadequate to assure and  
 6 preserve its identity, strength, quality, and purity ..."

7  
 8 (ii) Defendants manufactured, processed, packed and/or held, and Gilead held and  
 9 distributed, drug product that did not come with the assurance of identity, strength,  
 10 quality and purity required for approval and distribution under the FDCA, and  
 11 Defendants lied to the FDA in order to conceal their inability and/or unwillingness to  
 12 correct these failures. Therefore, drugs manufactured for sale by Defendants were not  
 13 "covered" by Medicare, Medicaid and other government health programs under the  
 14 Social Security Act and all claims for those drugs during the times relevant to this  
 15 complaint were false. Examples of the methods, facilities and controls used in the  
 16 manufacture, processing and packing of drugs at the Defendants that were inadequate to  
 17 assure and preserve their identity, strength, quality, and purity are set forth below.  
 18  
 19  
 20  
 21

22 **(E) DRUG PRODUCT NOT MANUFACTURED IN ACCORDANCE WITH**  
 23 **NDAS**

24 42. 21 U.S.C. §§ 355(b)(1)(B)-(D) provides that applications to the FDA for approval of new  
 25 drugs ("NDAs") must include: "(B) a full list of the articles used as components of such  
 26 drug; (C) a full statement of the composition of such drug; (D) a full description of the  
 27 methods used in, and the facilities and controls used for, the manufacture, processing, and  
 28

1        packing of such drug[.]” Approval by the FDA of this drug formula and method of  
2        manufacture is required for introduction of the drug in interstate commerce and  
3        distribution for human use. 21 C.F.R. §§ 314.70 and 314.81 respectively require  
4        manufacturers to obtain FDA approval for, or make the FDA aware of, changes in the  
5        conditions established in an approved application.  
6

7        (iii) As a result of the chronic, serious deficiencies in the quality assurance function at  
8        Defendants' plants and the Defendants' ongoing serious violations of the laws and  
9        regulations designed to ensure the fitness of drug products for use, Gilead released to the  
10       market, to which Gilead Alberta enabled, drugs that were not manufactured in accordance  
11       with the NDAs filed with the FDA in that, to Defendants' knowledge within 31 U.S.C.  
12       Sec. 3729(b), the components, composition and/or methods and controls used in  
13       manufacturing, processing and/or packing had been changed without FDA approval  
14       and/or knowledge. At a minimum, as a result of Defendants' inability to control critical  
15       factors that cause variability in the manufacturing process, Defendants were recklessly  
16       indifferent to whether, and could provide no assurance that, their manufacturing  
17       processes were capable of consistently producing products that met approved  
18       specifications. Therefore, drugs manufactured by Defendants were of unknown safety  
19       and effectiveness and were not "covered" drugs for the purpose of Medicaid and other  
20       government health plans under 42 U.S.C. 1396r-8(k), and all claims for those drugs  
21       during the times relevant to this complaint were false. Examples of the chronic, serious  
22       deficiencies in the quality assurance function at the Defendants' plants and the  
23       24       25       26       27       28

Defendants' ongoing serious violations of the laws and regulations designed to ensure the fitness of drug products for use are set forth below.

### **DAMAGE TO THE GOVERNMENT**

43. The Relators do not know the precise extent of the financial damage suffered by Medicaid, Medicare, the VA, and other government health programs arising from the knowing submission of false claims by the defendants in this action. However, the Relators believe that the damages amount to billions of dollars, based on the following:

(a) the violations were significant and systemic, affecting key aspects of the Defendants' plants' operations including the quality assurance units, and defective products were released to the market and paid for by the government as a result; (b) virtually all of the drug products manufactured and sold by the defendants were impacted, representing billions in sales each year; (c) significant amounts of Gilead's drug products are sold in the United States; and (d) federal and state governments purchase the majority of prescriptions sold domestically. During the times relevant to this complaint, Gilead's drugs Viread, Viread Oral Powder, Emtriva, Emtriva Oral Solution, Truvada, Hepsera, Atripla, Complera, and Stribild, all domestic sales of which are subject to the claims herein, were the top selling HIV/AIDS drug products in the world.

44. In 2008 and 2009 alone, the following quantities of Gilead drug products were purchased by the federal government:

- A. Atripla: \$3.2 billion, representing 2.8 million bottles;
- B. Truvada: \$2.6 billion, representing 3.3 million bottles;

- C. Letaris: \$329 million, representing 36,000 bottles;
- D. Viread: \$929 million, representing 1.3 million bottles;
- E. Emtriva: \$518 million, representing 118,000 bottles; and
- F. Hepsera: \$385 million, representing 422,000 bottles.

## **PARTICULARS OF FALSE CLAIMS ACT VIOLATIONS**

### **Background**

45. Defendants maintain unacceptably poor manufacturing practices for all, or virtually all, of Gilead's assorted drug products and the APIs contained within them. Defendants continually and knowingly channeled contaminated and adulterated drug product into the clinical and commercial marketplaces, and actively and aggressively conceal their poor manufacturing practices and contaminated products from their regulatory authority—the FDA—and their customers/payors, including various government agencies.
46. These systemic violations are neither victimless nor merely technical. Defendants poor manufacturing practices and cover-ups result in drug products with significant, observed contaminations and excursions entering the nation's pharmaceutical supply chain destined for a highly vulnerable population of patients. "adverse events" associated with "product problems" in both the clinical setting and prescribing populations are inevitable.
47. In this amended complaint, the Relators describe numerous examples; some involving API used in the manufacture of FDA-approved, commercially-sold drugs for patients with HIV/AIDS, Cystic fibrosis, and other immuno-compromised populations; others involving clinical drugs provided to patients in studies conducted in support of NDAs and

1 supplemental NDAs, which NDAs and supplements have been approved and the  
2 compromised drugs subsequently sold commercially.

3 **I. UNAPPROVED, ADULTERATED DRUG PRODUCTS FROM UNREGISTERED**  
4 **MANUFACTURING FACILITIES**

5 48. In its ongoing effort to maximize profits at the expense of product safety, Gilead has  
6 twice (at least) contracted with new manufacturing facilities, and started to use the  
7 facilities' end products (APIs) in commercial sales and testing regimens, years before  
8 gaining approval of the new facilities as API manufacturers with the FDA. Failure to  
9 make timely and accurate registration of a new manufacturing facility renders all sales  
10 containing product manufactured in that facility unapproved and the product misbranded  
11 under the FDCA. 21 C.F.R. § 314.50(d)(1)(i); 314.70(b)(2); 21 U.S.C. § 360(i) and (j).  
12

13  
14 49. As reflected below, these schemes, omissions and delays were material, as manufacturing  
15 processes at the unregistered facilities were flawed, resulting in instances of known  
16 contaminated product that Gilead nevertheless released into the commercial marketplace  
17 prior to FDA approval.  
18

19  
20 50. Gilead concealed the contamination issues from the government in order to gain its  
21 approval of the new facilities. If the government were aware of the contamination issues,  
22 or of Gilead's use of manufactured product prior to FDA approval, it would not have  
23 approved the facilities, or approval would have been revoked.  
24  
25  
26  
27  
28

**A. SYNTHETICS CHINA LTD. BEGAN PRODUCTION OF CONTAMINATED FTC WHICH GILEAD USED FOR COMMERCIAL SALE BEFORE THE FDA APPROVED THE NEW FACILITY**

51. In or around 2008, Gilead contracted with the firm Synthetics China, LTD. ("Synthetics China") to manufacture the API emtricitabine (commonly known as "FTC"), the active ingredient in many of Gilead's HIV/AIDS drug products, including Emtriva, Emtriva Oral Solution, Truvada, and Atripla, and several clinical trial drugs. [REDACTED]

52. To save money, [REDACTED] [REDACTED] Gilead began to use the FTC manufactured by Synthetics China in commercial sales even though the Chinese company had not been authorized by the FDA, had never been inspected by the FDA, and did not have a mandatory National Drug Code ("NDC") labeler number. [REDACTED]

[REDACTED] During the time period in question, the NDC labeler number was required for reimbursement of Gilead drug products manufactured using Synthetics China API under Medicare / Medicaid programs. For the reasons listed, the defendant was not permitted to supply API for use in drugs sold in the United States.

53. Ultimately, in October 2009, Gilead received approval from the FDA of Synthetics China as an API manufacturer and in early (March/April) 2010 Synthetics China received its NDC labeler code identifier. But products from a new manufacturing facility cannot be

1 used until after such approval has been given, and Gilead began using product from  
2 Synthetics China at least two years before receiving approval of the facility from the  
3 FDA. 21 C.F.R. § 314.70(b)(2), (3). Gilead failed to inform the FDA that it was already  
4 using batches of finished drug products containing FTC manufactured by Synthetics  
5 China.  
6

7 54. In its rush to gain approval of Synthetics China as an API manufacturer, Gilead cut  
8 corners in the application process, manipulating the required validation studies and  
9 concealing evidence from the FDA that Synthetics China's manufacturing processes were  
10 flawed, and that the FTC it produced was contaminated and impure.  
11

12 55. At least some of the contaminated product was sold commercially even after Gilead  
13 identified these contaminants, and well before the FDA approved Synthetics China as an  
14 API manufacturer. To mask its conduct, and to begin selling API from Synthetics China  
15 before FDA approval, Gilead further schemed to import the API from Synthetics China  
16 through Gilead's Canadian facilities at Gilead Alberta under false auspices, and to  
17 conceal its origin by crediting it to an approved API manufacturer rather than to its actual  
18 origin in China.  
19  
20  
21

22 **(1) False Application for Approval of Synthetics China**  
23

24 56. Gilead submitted its initial application for approval of Synthetics China as an API  
25 manufacturer of FTC on October 20, 2008. [REDACTED]  
26

27 As reflected in the application, Gilead asserted that three full-commercial-scale batches  
28 of FTC had been manufactured at Synthetics China that passed testing and were

consistent with, and equivalent to, batches manufactured at existing approved sites.

57. These representations were false. Two of the three Synthetics China validation batches in fact failed internal testing.<sup>2</sup> Gilead eventually amended its application with different validation batches, but never disclosed the failure of the initial batches to the FDA.

A. A certificate of analysis from Synthetics China for lot 107201, the first of the validation batches, shows that this batch contained residual solvent levels in excess of established limits. The COA is dated January 17, 2008, some 10 months before Gilead submitted its application for approval of Synthetics China as an approved API manufacturer using this very batch as one of three validation lots.

B. A series of COA's from September 2008 certificate of analysis from Synthetics China for lot 1080904 ("lot 904"), the second of the validation batches, reflects another FTC batch with questionable properties. Gilead investigated the microbial contamination in October 2008 – around the same time that it applied to qualify

<sup>2</sup> In this respect, and this respect only, there was consistency and equivalence between the failed lots manufactured by Synthetics China and FTC manufactured at other approved sites. Some of the very batches from the other facilities to which the Synthetics China lots were compared also were known by Gilead to contain contaminants and impurities. For example, the lots manufactured by existing supplier Yuhan that are identified in the Synthetics China application contained black particles that were the subject of investigation by Gilead and several lots listed from Evonik Industries required numerous retests to determine the level of impurities.

<sup>3</sup> Oddly, the values of the impurities in Gilead's internal reporting documents changed over time, indicating that Gilead was attempting to re-test the batch into compliance. After testing and re-testing this batch for over two years after its original production date in late 2007, Gilead ultimately concluded that it had indeed failed.

1 Synthetics China as an approved facility, using this very lot to validate the application –  
2 and completed a worksheet in January 2009 acknowledging that the contamination was  
3 "higher than we typically see for this material." [REDACTED] While the total aerobic  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]

8  
9 A. Two different micro-organisms were found in the batch, including one – *bacillus*  
10 *cereus* – that can be potentially fatal in an immuno-compromised population. Although  
11 the investigation "did not show any definable cause for the organisms," Gilead's  
12 investigators nevertheless concluded (somehow) that the problem was "specific to lot  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]

16  
17 B. This same lot also failed in metal content due to the presence of arsenic, chromium  
18 and nickel contaminants [REDACTED] and failed  
19 accelerated stability testing [REDACTED] Inexplicably, despite all of these known  
20 impurities and failures, and while deciding that lot 904 would no longer be used as a  
21 validation lot for FDA approval, Gilead nevertheless released the batch for final drug  
22 processing and, ultimately, commercial sale. [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27  
28

1 58. While confirming the presence of metals and other impurities in Synthetics China's  
2 manufactured API product, and while FDA approval of Synthetics China was not  
3 received until early 2010, Gilead, with the approval of management, requested that  
4 "routine production" of FTC at Synthetics China in 2009 continue, and resolved merely  
5 to "monitor metal levels" and "monitor arsenic levels" as if the presence of the industrial  
6 contaminants was acceptable at any level. [REDACTED]  
7

8 59. There is no indication that Gilead determined, or required Synthetics China to determine,  
9 where these heavy metal contaminants were introduced or to rid the manufactured API of  
10 them entirely.  
11

12 60. As for its application to the FDA for approval of Synthetics China, although it was still  
13 learning yet more about the failures of the original validation lots, Gilead resolved to  
14 amend the application rather than withdraw it. [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]

19 61. New Gilead certificates of analysis were created to brush over problems and  
20 inconsistencies identified by Relator Jeff Campie with the original Synthetics China  
21 COAs as they pertained to the replacement validation lots. [REDACTED]  
22

23 [REDACTED] Gilead proceeded, at the direction of management, to submit  
24 the data from subsequently manufactured (after the initial FDA filing) batches of FTC  
25 API to the FDA to avoid disclosing the failures associated with the release and stability  
26 data of the original lots. [REDACTED]  
27  
28

**(2) Commercial Sale of Synthetics China Product Before Approval**

62. In the meantime, Gilead was releasing the FTC manufactured at Synthetics China to its CMOs, and then releasing finished product for commercial sale, all well before the FDA approved Synthetics China as an API manufacturer, and without disclosing this activity to the FDA, in the prior approval supplement or any amendments thereto.

63. In addition to contaminated lot 904 discussed above, which was released for sale in 2009, the following are examples of the many batches of Synthetics China FTC that were used by Gilead to manufacture, release and sell finished drug product well prior to FDA approval of Synthetics China.

A. Synthetics China lot 1080905 – the third of the original validation batches, and still a validation lot in Gilead's "amended" application – was manufactured in September 2008; and released for "human use (commercial)" on May 14, 2009. [REDACTED]

Batches of final drug product containing this FTC from Synthetics China were released for sale by Gilead in 2009. [REDACTED] again, the FDA did not approve Synthetics China as a manufacturing facility until early 2010;

B. Another replacement validation lot – Synthetics China lot 1081006 – was released for commercial human use in May 2009 [REDACTED] Batches of final drug product

containing this FTC from Synthetics China were released for sale by Gilead in 2009.

64. As summarized in a November 2009 internal annual quality review, no fewer than [REDACTED] lots of FTC API manufactured at Synthetics China were released by Gilead from September 2008 to August 2009. [REDACTED] Of the [REDACTED] lots, most were incorporated into finished drug products and sold commercially, including contaminated lot 904 and the other lots in the examples above. [REDACTED] One lot was relegated to use in a clinical study (but not recalled) due to out-of-trend results for density and for containing [REDACTED] and assay, and three lots were "rejected for reprocessing" (but not destroyed) due to unspecified impurities. [REDACTED]

65. In short, despite the known production flaws at Synthetics China, and despite not having the approval of the FDA for any of the manufacturing there, Gilead released and used scores of lots of API manufactured at Synthetics China, representing thousands of kilograms, and apparently did not find cause to destroy or recall any product despite these known manufacturing problems.

66. An October 2012 Assessment Report, [REDACTED] [REDACTED] which was approved by senior management from the Gilead Alberta facility contains specifics of [REDACTED] (purported to have begun in 2009) and undertaken without the benefit of a governing standard operating procedure. The report largely contained material inaccuracies and omissions in

an attempt to cover up Alberta's role in the company's use of tainted Synthetics China  
FTC API.

67. Redundant testing and the generation of duplicate API COA's. [REDACTED]

While the report is intended to make it appear as though the practice of redundant testing  
is both commonplace and cGMP, nothing is further from the truth. With both Gilead's  
[REDACTED] and the FDA approval of the Synthetics China operation, there should have  
been no need to retest if suitable material was being produced and released by a  
compliant laboratory—as repeatedly stated in the reports. Further, the practice of  
duplicate COA's is not specific to Synthetics China [REDACTED] and while  
commonplace in the company, is not compliant, as noted by a former FDA inspector  
[REDACTED] as the practice of re-creating COA's can mislead one into perceiving the  
source of the analytical testing.

68. New Impurities and Gross Contamination: New chemical impurities such as the  
[REDACTED] elevated levels of the heavy metals  
lead and arsenic, [REDACTED] and gross contamination have been well documented in  
numerous internal emails, documents, reports, and this complaint. In the 2009-2013  
timeframe, the Gilead Alberta site was integral in sieving out foreign matter (glass, rocks,  
etc.) from scores of lots of FTC API from Synthetics China. Of note, the approver of the  
*Assessment Report* (Lishi Ying) was also copied on Tammis Matzinger's November 24,  
2011 *Summary of FTC INC-056 Investigation Activities at Gilead Alberta* internal memo  
which captured the tasks of sieving and photographing foreign matter later classified as

“glass-like shards,” “black, rubber-like, particles,” “plastic-like particles,” “small stone or pebble-like particles,” and “metal shards” [REDACTED] activities undertaken at the very facility (Gilead Alberta) in which Mr. Ying was employed as a director. [REDACTED]

### (3) Gilead Conceals Use of Synthetics China Product During Approval Period

69. Gilead actively attempted to conceal from the FDA its reliance on and use of FTC manufactured by Synthetics China during the FDA's review process, knowing that use of such product before approval was improper.

70. First, Gilead schemed to import the API from Synthetics China through Gilead's Canadian facilities – defendant Gilead Alberta – as API supporting Investigational New Drug (“IND”) activities, rather than API for commercial sales that the Synthetics China product was really being used for. [REDACTED]

71. The labeling and paperwork reflecting the product's genesis at Synthetics China was obscured/augmented by Gilead Alberta shipping labels and paperwork designed to effectively conceal where the API was actually produced.

72.

review of Gilead's application for Synthetics China, Gilead was crediting approved manufacturer Yuhan (of South Korea) with production of FTC that was actually produced at Synthetics China. [REDACTED] The document indicates that Yuhan produced no FTC during this time period. Yet Yuhan is credited in the document with shadow "production" that exactly matches – *to the kilogram* – the actual production at Synthetics China.

73. During the referenced timeframe (December 2007-August 2008), Yuhan was FDA-approved to manufacture FTC API. Synthetics China was not. Gilead endeavored to make it appear that Yuhan was manufacturing FTC that was actually coming from Synthetics China so as to avoid detection by the government. [REDACTED]

74.

each instance, lots from Synthetics China were receiving a second ICN from an approved manufacturer, such as Yuhan. Notably, the Synthetics China ICN's possessed codes reflecting that the product had a restricted use, while the Yuhan ICN's were coded to reflect their suitability for U.S. commercial sale. With the interchangeability of the ICNs, Gilead could push through Synthetics China product under the guise of coding that indicated its suitability for commercial sale.

1 75. Gilead violated 31 U.S.C. § 3729(a)(1) (b) and equivalent provisions of state laws by: (i)  
 2 removing the IND label from FTC imported from Synthetics China; (ii) relabeling FTC  
 3 imported from Synthetics China as "human use (commercial)"; and (iii) knowingly  
 4 submitting a Prior Approval Supplement that contained material false statements and  
 5 omissions, as detailed above.  
 6

7 76. Gilead's fraud in the IND labeling and prior approval supplement infects every batch of  
 8 final drug product in which Synthetics China's API was included, including Emtriva,  
 9 Truvada and Atripla. All batches that included API manufactured by Synthetics China  
 10 were unapproved for sale in the United States.  
 11

12 77. All claims that Gilead presented, and caused others to present, to the federal or state  
 13 governments from sales of these drugs violated 31 U.S.C. § 3729(a)(1)(a) and equivalent  
 14 provisions of state laws.  
 15

16 **B. USE OF GILEAD ALBERTA, A CANADIAN FACILITY, TO**  
 17 **MANUFACTURE API PRIOR TO FDA APPROVAL OF NEW FACILITY**

18 78. Gilead also used its Canadian facility – Gilead Alberta – to manufacture a different API  
 19 from 2007 until 2009 which the facility was not approved and was not registered to  
 20 manufacture, yet which API was nevertheless released for use in the manufacture of  
 21 Gilead's drug Letairis.  
 22

23 79. Relator Jeff Campie informed Gilead management that it would be illegal to market  
 24 Letairis manufactured from API produced at the unregistered Canadian site. Jeff Campie  
 25 attempted to have batches of Letairis located at Gilead's San Dimas facility quarantined  
 26 until approval from the FDA was secured, but Gilead insisted on maintaining the drug in  
 27  
 28

1 release status and available for commercial sale. Mr. Campie was rebuked for the  
 2 warnings by Tony Caracciolo, Gilead's Senior Vice President for Manufacturing and  
 3 Operations.

4  
 5 80. After initially rejecting Gilead's application for the Canadian facility in April 2009, the  
 6 FDA ultimately approved it in late October 2009. But this approval was based upon  
 7 misinformation and omissions in Gilead's application, including representations that the  
 8 canadian facility was not yet being used for the manufacture of product for clinical use or  
 9 commercial sale when in fact it was. The following documents and chronology support  
 10 these claims.  
 11

12 (1) Use and Sale of Gilead Alberta Product Prior to Approval

13  
 14 81. Gilead first sought approval from the FDA to use Gilead Alberta as a manufacturer of  
 15 ambrisentan drug substance, the API in Letairis, in October 2008. [REDACTED]  
 16 [REDACTED]  
 17 [REDACTED]  
 18 [REDACTED]  
 19

20 82. The FDA rejected Gilead's CBE-30 application on April 15, 2009, on the grounds that the  
 21 application lacked stability data. [REDACTED] The FDA further informed Gilead that it  
 22 was inappropriate to apply for approval of a new manufacturing facility with a CBE-30  
 23 application. [REDACTED]  
 24 [REDACTED]  
 25

26 83. CBE-30 applications – which permit the applicant to begin the applied-for activity 30  
 27 days after submission even if there has been no response from the FDA – can only be  
 28

utilized under certain limited conditions. 21 C.F.R. 314.70(c). For new manufacturing facilities, including foreign facilities, the FDA requires an inspection and approval before product from the site may be used in commercial or clinical product. FDCA, § 510 [21 U.S.C. § 360]; 21 C.F.R. § 207.40.

84. Thus, it is improper for an applicant to use a CBE-30 application for a new manufacturing site, and it is improper for the applicant to begin using product from that facility 30 days after the application is submitted on the assumption that the application will be approved.

85. In late April 2009, Gilead supplemented its application with stability data. The FDA finally issued its approval of Gilead Alberta as a manufacturer of ambrisentan in late October 2009.

86. In reality, Gilead had actually begun to manufacture ambrisentan at Gilead Alberta in June 2007, over a year before submitting the CBE-30 application. [REDACTED] listing three validation batches manufactured in June 2007 with lot numbers ending in 2P, 3P and 4P, highlighted in yellow; [REDACTED] Indeed, during 2007, Gilead Alberta was the only manufacturing site for ambrisentan, a fact which Gilead acknowledged in its 2007 10k [REDACTED] but did not disclose to the FDA in its subsequent CBE.

87. Gilead failed to disclose, in its CBE-30 application or otherwise, that the same API validation batches listed in the application were actually *released* by Gilead for the manufacture of clinical trial material and used in ongoing clinical studies in 2008, at the

1 same time that Gilead was submitting the application and well prior to the FDA's ultimate  
2 approval in November 2009.

3 88. For example, the certificate of analysis for the ambrisentan batch ending in "4P," one of  
4 the validation lots in the CBE-30, shows that Gilead Alberta completed testing on the  
5 batch in August 2007. [REDACTED] The "4P" batch was sent to Patheon for inclusion in  
6 finished drug product – a batch evaluation report shows that Patheon completed its  
7 manufacturing process using the Gilead Alberta 4P API in March 2008. [REDACTED]

8 89. The final drug product made from this same batch of API – now carrying the lot number  
9 linked to the Gilead Alberta API number "4P" in [REDACTED] – was released for labeling  
10 beginning in July 2008 [REDACTED] and finally for clinical (human) use on October 10,  
11 2008 [REDACTED] the specific clinical study in which the drug  
12 was to be used is referred to as trial "AMB-323" in the MSN.

13 90. Finally, [REDACTED]  
14 [REDACTED] the study was  
15 completed in May 2009, and that final data collection for primary outcome measures  
16 concluded by July 2008. Thus, the Letairis tablets manufactured with Gilead Alberta API  
17 (batch 4P) were used in final drug products released and used in clinical study AMB-323  
18 during 2008 and no later than early 2009.

19 91. At the same time, Gilead was completing its internal validation and approval activities for  
20 the use of Gilead Alberta in *commercial* manufacturing of ambrisentan. [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED] It is not GMP to use  
7 API material in a validation activity from a manufacturing site until after the site has been  
8 inspected and approved.  
9

10 92. Thus, Gilead permitted Gilead Alberta API to be used for clinical studies on human  
11 subjects, and approved its use in the manufacture of commercial lots, before even  
12 applying for FDA approval of the site and long before receiving approval.  
13

14 93. By the time the FDA rejected Gilead's application in April 2009, Gilead had already  
15 released no fewer than [REDACTED] batches of Gilead Alberta-manufactured ambrisentan API  
16 for clinical use, and [REDACTED] batches for commercial use. [REDACTED]  
17 [REDACTED]  
18

19 94. In July 2009, four months before the FDA responded to Gilead's supplemental  
20 application and approved Gilead Alberta as a manufacturing site, Gilead approved the  
21 release for commercial sale of numerous commercial lots of Letairis incorporating the  
22 Gilead Alberta-manufactured API. [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28

95. Accordingly, despite the FDA's denial of its application, the FDA's rebuke that Gilead should not assume that Gilead Alberta product could be used pending FDA approval, and the Relators' warnings and protests, Gilead still went ahead and shipped Letairis containing Gilead Alberta API for commercial sale in July 2009, months before receiving FDA approval.

(2) Concealed Flaws in Gilead Alberta Products

96. Making matters worse, Gilead knew that some, or perhaps all, of these early releases were of questionable quality.

97. One of the releases is worth particular mention. In June 2007, Gilead Alberta completed its first batch of ambrisentan, with lot number ending in 1P, which it designated for "engineering use" only. [REDACTED]

98. Yet just nine days later, Gilead issued a MSN for the engineering lot 1P, releasing it for "human use (clinical)," [REDACTED] which it ultimately was used for as evidenced by Gilead's internal ledger. [REDACTED] The Relators have seen no explanation for this extraordinary change in Gilead's disposition plan, and no justification for subjecting human test subjects to API that Gilead itself deemed to be unsuitable for human use.

99. Gilead's internal quality control and assurance documents evidence that it had difficulty and concerns with the quality of additional batches and lots of Gilead Alberta product

during the application process. [REDACTED]

[REDACTED] Each of these events took place before the FDA approved Gilead Alberta as a manufacturer of ambrisentan. The Relators have seen no evidence that these issues were disclosed to the FDA.

100. Products from a new manufacturing facility cannot be used until after such approval has been given, and Gilead began using product from Gilead Alberta at least two years before receiving approval of the facility from the FDA. 21 C.F.R. § 314.70(b)(2), (3).

101. In fact, Gilead had *already* begun to receive patient complaints on commercial drug product which had used the Gilead Alberta API *prior* to receiving FDA approval. [REDACTED]

102. All claims that Gilead presented, and caused others to present, to the government for sales of drugs that incorporated ambrisentan manufactured at Gilead Alberta prior to that facility being approved by the FDA violated 31 U.S.C. § 3729(a)(1)(a) and equivalent provisions of state laws.

## II. CONTAMINATION AND ADULTERATION IN COMMERCIAL DRUG PRODUCTS

103. As reflected herein, the defendants had ongoing problems with contaminants in their API and final drug products. Gilead knows about these problems and has documented them extensively, yet takes active steps to: (i) conceal the issues from the government; and (ii) avoid destroying contaminated batches or recalling drugs that have already been sold commercially.

1 104. Despite the amount of drug products that it sells and despite the sensitivity of the ultimate  
 2 patient population, Gilead has never recalled any drug product, and has never destroyed  
 3 any significant quantity of API or final drug product prior to sale — telltale signs that  
 4 Gilead is manipulating the process to maximize profits.  
 5

6 **A. ALL OR MOST GILEAD DRUGS MANUFACTURED WITH FTC**  
 7 **CONTAIN KNOWN BUT UNDISCLOSED INGREDIENTS,**  
 8 **ADULTERATIONS, AND MATERIAL CONTAMINATIONS CAUSED BY**  
 9 **GMP DEFICIENCIES**

10 105. Many of Gilead's primary drug products, including Emtriva, Emtriva Oral Solution,  
 11 Truvada, and Atripla, as well as combination drugs derived from these drug products, are  
 12 based on FTC as one of their component APIs. The FTC used by Gilead in its final drug  
 13 products is produced by various API manufacturers.

14 106. Gilead obtained FDA approval for Emtriva, Truvada and Atripla between July 2003 and  
 15 July 2006.  
 16

17 107. Gilead's new drug applications ("NDAs") for each of these drugs listed FTC as an active  
 18 ingredient and also listed specific inactive ingredients. For each approved drug, the FDA  
 19 required that "the final printed labeling must be identical to the enclosed labeling," both  
 20 in terms of active and inactive ingredients. In other words, the component ingredients of  
 21 every batch of final drug product must be identical to those listed in the NDAs.  
 22 Additional, undisclosed ingredients are not permitted. Such product is considered as  
 23 "misbranded" and the actions are in violation of the FDCA (sec 502)(title 352).  
 24  
 25

26 108. Prior to gaining FDA approval for these final drug products, and contrary to the  
 27 statements in its NDAs, Gilead knew that FTC supplied by its various manufacturers  
 28

1 contained process impurities that altered the chemical makeup of the final drug products.  
2 These alterations and adulterations were not disclosed to the FDA even though the FTC  
3 and final drug product manufactured with it contained ingredients that, due to the  
4 contamination, were not part of the list of approved ingredients.  
5

6 **(1) Gilead Knew That Lack Of Adherence To The GMPs Would Result In**  
7 **Contaminates Forming In FTC-Based Drugs No Later Than 2002**

8 109. On December 16, 2002, Gilead formalized the purchased of Triangle Pharmaceuticals  
9 and with it, assumed ownership of the NDA for what had previously been Coviracil  
10 capsules. On July 2, 2003, the FDA granted Gilead approval for Emtriva (formerly  
11 Coviracil) capsules. However, Gilead and Triangle had begun discussing possible  
12 transactions and co-formulation relationships no later than August 2001. [REDACTED]  
13

14 By late 2002, the company had conducted scientific 'due diligence' and had made an  
15 offer to purchased Triangle Pharmaceuticals contingent on Triangle providing Gilead  
16 with any material communications with—and submissions to—the FDA regarding  
17 Emtricitabine. [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]

22 [REDACTED] Subsequently, in 2005, Gilead submitted an NDA for Emtriva  
23 Oral Solution, an aqueous form of the previously-approved Emtriva capsule formulation  
24 for use in the pediatric population. In support of the NDA, Abbott Laboratories prepared  
25 version 7 of the Analytical Research Method for Emtricitabine, the API in both Emtriva  
26 capsule and oral solution preparations. [REDACTED]  
27 [REDACTED]  
28

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Gilead/Triangle/Abbott may

not have identified the [REDACTED] impurity by name leading up to the July 2003 approval, but they certainly knew its properties and its presence in both the API and final drug product.

110. In October 2003, prior to gaining FDA approval for Truvada, the company detected foreign particles characterized as black specks in registration batches of Truvada tablets.

[REDACTED] Within several months, a March 2004 stress study confirmed that the presence of the [REDACTED] impurity [REDACTED] was associated with the FTC compound when exposed to humidity or elevated temperatures. Thus, in the months of testing between 2003 and 2004, Gilead's analytical chemists and quality management observed the contamination with the naked eye in the form of charred and degraded particles in FTC and in blends containing FTC, both in tablet cores and in bulk tablets, and confirmed the chemical makeup of the impurity.

111. This same impurity, which cannot be observed using the traditional, FDA-approved purity tests, nevertheless has been detected numerous times in internal investigations involving Gilead's FTC-based drugs such as Truvada, Atripla and Complera. [REDACTED]

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED] as [REDACTED] continued to be detected at various  
4 temperature and humidity conditions, including those *within* FDA-approved  
5 environmental ranges.  
6

7 112. Beginning no later than 2003, most, if not all, batches of FTC used to manufacture  
8 Emtriva, Truvada, and the subsequently approved HIV/AIDS drugs Atripla and Complera  
9 were adulterated with a variety of unapproved contaminants, including the [REDACTED]  
10 impurity. [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]

15 the discovery of foreign matter in a series of clinical and primary stability batches of  
16 TDF/FTC tablets.  
17

18 113. Once the FDA issued its approval of the FTC-based drugs, Gilead knowingly released  
19 drugs contaminated with [REDACTED] for commercial sale and clinical use  
20 notwithstanding Gilead's discovery of the impurity and its intentional non-disclosure to  
21 the government. Throughout this period of time, Gilead failed to amend its NDA  
22 applications or disclose the existence of the contamination to the government.  
23

24 114. Although the company did not routinely test for [REDACTED] prior to 2010, the company  
25 was aware that there was a direct correlation between elevated levels of [REDACTED] and the  
26 formation of [REDACTED] in FTC-based drugs years earlier as FTC drug  
27  
28

substance stability samples tested by Gilead at recommended storage temperatures (25C/60RH) showed traces of FTU after only [REDACTED] months of storage [REDACTED] and failed room temperature testing after [REDACTED] months. [REDACTED] By late 2003,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] However, nothing was reported to the FDA regarding the stability failures. Rather, the same API lots that were failing internal specifications were being used in the manufacture of Clinical Supply, Scale-Up, and Primary (registration).

115.

[REDACTED]

[REDACTED]

[REDACTED] In

spite of the failures on stability, the same lot of API (lot PP-0046-3001) was used in a subsequent campaign to manufacture TDF/FTC tablet lot V308B1 months later. [REDACTED]

[REDACTED]

116. Therefore, Gilead was negligent by not investigating the level of [REDACTED] present in all FTC-based drugs that failed for levels of [REDACTED].

1 117. Notwithstanding its knowledge of these results, Gilead failed to initiate any valid  
2 toxicological testing to assess the long-term health consequences of the contamination  
3 and failed to establish a testing method for measuring the level of [REDACTED] impurities.

4  
5 118. Moreover, in 2005, Gilead filed a Prior Approval Supplement ("PAS") with the FDA for  
6 approval of the sale of Truvada for additional government programs. While disclosing  
7 obliquely in the PAS that "new degradation product(s)" had been detected, Gilead falsely  
8 stated that the degradation had *not* been observed in tablets stored for six months at  
9 40C/75RH. [REDACTED] By 2005, degradation had in fact been observed, both at this  
10 elevated temperature range and in the normal range as well. Gilead's misrepresentation  
11 facilitated the FDA's approval of the Prior Approval Supplement, thus qualifying  
12 Truvada for the federal government's PEPFAR program under false pretenses.  
13  
14

15 119. In June and July 2006, Gilead again received independent complaints from two of its  
16 CMOs regarding black particles observed in one lot of Truvada [REDACTED] and one lot  
17 of FTC during the manufacture of Atripla. [REDACTED]  
18 [REDACTED]

19 [REDACTED]  
20 the analytical testing on the material), Gilead confirmed that the black particles in each  
21 instance were comprised of degraded FTC-related compounds – that is, [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24  
25  
26  
27  
28

1 120. [REDACTED]

2 [REDACTED]

3 [REDACTED] Gilead's testing further confirmed that the black particle impurities contained

4 [REDACTED]

5 [REDACTED]

6 121. Gilead ultimately determined that the contamination potentially impacted 19 batches of

7 API, which were incorporated into at least 19 batches of Truvada and 6 batches of

8 Atripla. [REDACTED]

9 [REDACTED]

10 122. Nevertheless, Gilead approved all lots for use in the manufacture and sale of Emtriva,

11 Truvada, and Atripla without further investigation and without any issuance of an FDA

12 field alert, and never initiated a product recall once the contaminated drugs were sold into

13 the commercial marketplace.

14 [REDACTED]

15 123. According to Gilead's Head of Toxicology, the black particles comprised of charred and

16 chemically altered FTC were merely "aesthetic defects." Gilead's Senior Vice Presidents

17 Taiyin Yang and Tony Caracciolo approved the determination to use the contaminated

18 API in final drug products for commercial sale and clinical trials. [REDACTED]

19 [REDACTED]

20 124. For example, one of the [REDACTED] batches of FTC manufactured by Yuhan and investigated in

21 2006 was PP-0053-5044 ("lot 5044"). Lot 5044 was among the Yuhan FTC API lots that

22 were both visually contaminated and failed potency and purity testing, but was

23 nevertheless utilized in commercially distributed drug product.

24 [REDACTED]

25 [REDACTED]

26 [REDACTED]

27 <sup>5</sup> Mass Balance refers to reconciling the initial purity of a compound, typically (approximately) 100% against the purity (plus

28 all observed impurities) at the end of the process. Acceptable values are generally seen as +/- 1.0% range (99.0-101.0%).

1 125. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED] Gilead selectively tested lot 5044 as well,

6 confirming the potency and purity failures. [REDACTED] [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 126. Again, despite these test results, Gilead somehow concluded in the FTC Summary report

14 that lot 5044 and the other [REDACTED] lots of contaminated Yuhan FTC API would be released.

15 [REDACTED]

16 "The investigation concludes that there is no product or API quality or safety

17 impact. The presence of extremely small amounts of the small FTC-related black

18 particles is an aesthetic defect. Product lots manufactured to date that pass all

19 specification limits are deemed acceptable. There are no restrictions to the use of

20 the remaining Yuhan FTC API lots subject to this investigation in commercial or

21 clinical product manufacturing" [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

26 127. Lot 5044, identified in the FTC report as one of several validation lots used in Gilead's

27 new "triple combo" formulation (also known as Atripla), was incorporated into finished

28 [REDACTED]

1 drug product and utilized in commercial sale. [REDACTED] It is clear that the company  
 2 simply rationalized a way to ignore the potency, purity and ongoing visual contamination  
 3 issues, and released the materials into commerce. The ultimate certification of the lot  
 4 5044 as passing all acceptance criteria differed from the company's prior testing, which  
 5 clearly indicated that the lot failed on various metrics.  
 6

7 **(2) Gilead's 2010 Disclosure to the Government of the [REDACTED]**  
 8 **Impurity Contained Falsified Data and Provided False Assurances of**  
 9 **Potency, Purity and Stability**

10 128. By 2010, Gilead had finally acknowledged to the FDA that [REDACTED] contamination  
 11 formed in Truvada and Atripla tablets even when stored at recommended temperature  
 12 ranges, and even when stored for as little as six months, facts which Gilead had known  
 13 since at least late 2002.  
 14

15 129. Notwithstanding this belated disclosure, Gilead assured the FDA that no field alert report  
 16 or recall was warranted [REDACTED] notwithstanding that: (i) the chemical composition  
 17 of the impacted drug products was clearly altered by the presence of [REDACTED], rising to  
 18 the level of "significant chemical, physical, or other change or deterioration in the  
 19 distributed drug product, or [a] failure ... to meet the specifications established for it in  
 20 the application," 21 C.F.R. § 314.82(ii); and (ii) no changes had been implemented in  
 21 Gilead's and its API manufacturers' manufacturing processes to bring them within cGMP,  
 22 even though the presence of [REDACTED] clearly indicated uncontrolled processes and  
 23 process changes.  
 24  
 25  
 26  
 27  
 28

1 130. In approximately July 2010, Relator Sherilyn Campie initiated a discussion with her  
 2 manager at Gilead suggesting that stability samples of FTC be tested for the presence of  
 3 [REDACTED] degradants due to the apparent lack of mass balance in samples under test.  
 4 The results from Ms. Campie's testing demonstrated that virtually all batches of FTC  
 5 supporting Gilead's clinical trial product and primary stability and registration activities  
 6 contained varying levels of the [REDACTED]. She further observed  
 7 that a batch of Atripla contained quantifiable levels of the [REDACTED] compound even  
 8 though it had been subjected to normal range (25C/60RH) conditions for just [REDACTED]  
 9 months. [REDACTED]

12 (3) **Gilead Discovers Additional Impurities Relating to FTC That It Also**  
 13 **Fails to Timely and Accurately Report to the FDA.**

14 131. In addition to [REDACTED] Gilead has detected a [REDACTED] impurity in numerous  
 15 batches of FTC that were subsequently released for commercial sale. This impurity was  
 16 observed in FTC manufactured at Synthetics China and Evonik. Again, the presence of  
 17 the impurity was confirmed in several reports and memos, but Gilead still approved the  
 18 release of the final drug products containing the impurities for human use. [REDACTED]

21 132. Moreover, during testing in late 2010, Relator Sherilyn Campie observed three other  
 22 unknown impurities in FTC in addition to the [REDACTED] impurity. [REDACTED]  
 23 [REDACTED]  
 24 [REDACTED]  
 25 [REDACTED]

26 133. Gilead has not attempted to quantify or qualify the unknown impurities. But it has  
 27 quantified the [REDACTED]. As demonstrated in the chromatogram, each of  
 28 [REDACTED]

1 the three unidentified impurity peaks far exceeds the [REDACTED] peak. Accordingly, the  
2 unidentified impurities exceed both the .10% reporting threshold for unidentified  
3 impurities and the .20% identification threshold as established by ICH guidelines. [REDACTED]  
4 [REDACTED]  
5 [REDACTED]

6 134. Rather than quantifying and reporting the values of the three unidentified impurities,  
7 Gilead instructed its lab technicians, including Ms. Campie, to ignore the peaks  
8 associated with those impurities. [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]

14 135. Gilead determined to ignore the three unknown impurities, to not quantify them, and to  
15 not report them to the FDA, even though they were present at room temperature storage  
16 conditions approved for Gilead drugs Atripla, Truvada, Complera and Stribild.  
17 [REDACTED]

18 136. In Gilead's amended NDA for Complera, submitted in February 2011, the company failed  
19 to identify or mention the existence of the three other unidentified degradation products  
20 observed during testing for [REDACTED]. All Gilead drug products that incorporate FTC  
21 as an API are impacted by these degradants at normal storage conditions, yet Gilead has  
22 not disclosed them to the government.  
23 [REDACTED]

24 137. [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

**(4) All of Gilead's FTC-Related Drugs Have Been Tainted By Undisclosed, Material Contamination from the Time of Gilead's NDAs Through the Present Time. Accordingly, All Sales of These Drugs Constitute False Claims.**

138. As described above, all of Gilead's NDAs for its drugs that incorporate FTC contained false statements and material omissions, in that they listed ingredients that did not include the [REDACTED] discovered no later than 2002, the [REDACTED] impurities discovered no later than 2009, and the three unknown impurities discovered no later than 2010. These false statements and material omissions were intentional, as Gilead knew about the impurities at the time of the respective NDA filings.

139. Gilead never submitted supplemental NDAs in order to obtain FDA approval for the inclusion of the contaminants in its final drug products.

140. If the FDA had known about the false statements and material omissions, or if had known that the drugs incorporating FTC had these impurities, it would not have granted approval of the new drugs, or would have withdrawn approval once it learned of them. 21 U.S.C. § 355(e)(5).

141. Gilead knew this to be true, which is why it decided not to disclose the impurities and contaminations to the government in its NDAs or in any subsequent disclosures.

142. All claims presented to the federal and state governments for these drugs constitute false claims for unapproved or fraudulently-approved drug productions in violation of the false claims act and similar state statutes.

1 143. All batches of Emtriva, Truvada, or Atripla manufactured with these contaminants were  
2 unapproved for sale in interstate commerce.

3 144. The presence of these unapproved contaminants renders these drugs "adulterated," as  
4 defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the  
5 sale of the adulterated and misbranded drugs constitutes a violation of the false claims act  
6 and similar state statutes.  
7

8 145. In addition, the federal government sponsored and/or funded numerous drug trials  
9 involving products produced with FTC. Gilead was required to identify and disclose any  
10 new or known impurity or degradants in the API supplied to these studies. Yet Gilead  
11 failed to disclose the known impurities and degradants identified above. Each such  
12 failure also constitutes a violation of the false claims act and similar state statutes.  
13  
14

15 **(5) Synthetics China's Continuing FTC Contamination Issues**  
16

17 146. Since approximately December 2010, Synthetics China has been using a new, larger  
18 facility to manufacture FTC for Gilead which, once again, is highly contaminated and  
19 impure.  
20

21 147. By at least November 2011, Gilead knew that commercial drug product incorporating the  
22 FTC from the new facility was contaminated with colored glass, cement and fibrous  
23 building materials, and other impurities.  
24

25 148. Even after discovery of the contamination, Gilead failed to institute a recall of the  
26 multiple batches of released, commercial product that it knew to be compromised.  
27  
28

1 149. Moreover, it appears that Gilead and its suppliers may be continuing to utilize the flawed  
 2 API in additional batches of finished drug product for commercial sale after attempting  
 3 inadequate, uncontrolled sieving to remove the impurities.

4 150. [REDACTED]  
 5 [REDACTED]  
 6 [REDACTED]  
 7 [REDACTED]  
 8 [REDACTED]  
 9 [REDACTED]  
 10 [REDACTED]  
 11 [REDACTED]

12 151. The new facility came to be known as Synthetics China's "Plant 203." [REDACTED]  
 13 [REDACTED]  
 14 [REDACTED]

15 [REDACTED] Plant 202, which was the original Synthetics China plant that  
 16 manufactured contaminated FTC for premature commercial sale, as detailed above).  
 17

18 152. In its December 2010 internal "Validation Report" for plant 203, [REDACTED]  
 19 Gilead explains that Plant 203 is a new plant at Synthetics China's existing location in  
 20 Taixing City, China, [REDACTED]  
 21 [REDACTED] Relying on three  
 22 consecutive FTC validation lots from the new plant (hereinafter referred to as "lots 151,  
 23 152 and 153"), Gilead concludes that [REDACTED]  
 24 [REDACTED]  
 25 [REDACTED]  
 26 [REDACTED]  
 27 [REDACTED]  
 28

153. Gilead and its suppliers have released commercial drug product incorporating FTC manufactured at Synthetics China's Plant 203 since approximately December 2010, when the process was deemed "validated." [REDACTED] [REDACTED] for FTC containing API from lots 152 and 153, reflecting disposition status of "released" for "human use (commercial).")

(a.) **Gilead Discovers New FTC Contamination at Plant 203**

154. By at least November 2011, after almost a year of commercial production, Gilead became aware that the very lots used to validate production at plant 203, among many others, were grossly contaminated by impurities. On November 9<sup>th</sup>, 2010, senior management at Gilead, including Tammis Matzinger (then Senior Director, Corporate Quality Assurance) and John Helms (Associate Director, Quality Control), urgently commenced testing on finished commercial product retain lots on stability that had incorporated FTC API manufactured at plant 203 with the "ICN-056" unit code. [REDACTED]

155. [REDACTED] and 153, two of the validation lots for Synthetics China's plant 203, and a total of nine batches of Gilead's AIDS drugs Truvada and Atripla, each comprised of over [REDACTED] bottles, that had already been released in the United States and elsewhere for commercial sale. At current drug prices, these sales alone represent over \$100 million to Gilead.

Gilead issued an FDA field alert regarding these lots but did not make any effort to recall them.

156. [REDACTED]

contaminated by "Pinkish-orange particles" identified as "Unidentified organic material" and "Brown paper strip" identified as "Brown paper." [REDACTED]

157. Relator Sherilyn Campie was not involved in the investigation or sample testing, but was informed by her colleagues in quality control who were involved that the panic was caused by the discovery of foreign particles in released commercial drug products. Pictures of what Gilead discovered upon dissolving samples of these products – the urgent testing mandated by Matzinger – shows that the concerns were entirely justified.

158. [REDACTED]

[REDACTED] These are the same lots in Matzinger's November 9 list that correspond to the validation API lots from Synthetics China's plant 203.

159. It did not take Gilead long to narrow its investigation of the contamination to FTC API manufactured at plant 203. [REDACTED]

160. [REDACTED]

1 [REDACTED]  
2 materials found in representative samples of released API and drug product as blue  
3 colored glass, cement and fibrous building materials, and metal shards. The largest piece  
4 weighs 39mg – 7.8% by weight of a Truvada tablet, or up to 19.5% of an Emtriva  
5 capsule. In parallel, all impacted tablet lots would have a proportionate decrease in  
6 potency arising from the substitution of API with the foreign matter.  
7

8 **(b.) Gilead Does Not Initiate a Recall and Continues to Use the**  
9 **Impure API**  
10

11  
12 161. The report also details the initial sieving and reprocessing activities undertaken by Gilead  
13 with respect to the contaminated API which was still on hand— [REDACTED]  
14 [REDACTED] (i.e., that which had not yet been incorporated and released in finished  
15 product). Entire lots of FTC were "sifted one drum at a time." As captured as [REDACTED]  
16 the results of the sieving were dramatic, with kilograms of material retained on the sieve  
17 representing substantial portions of the original material.  
18

19 162. Gilead separated out the retained material from the residual content, did some further  
20 testing on the residual, and then decided to utilize the API lots in commercial production.  
21 There is no indication in the report that any API was destroyed after sieving. To the  
22 contrary, Patheon facilitated Gilead's request to sift the tainted lots of FTC API by  
23 sending the batches to the Gilead Alberta facility, rather than requiring the lots to remain  
24 in Patheon control while awaiting destruction, as required under GMP regulations in both  
25 the United States and Canada. No drug product containing the contaminated FTC has  
26  
27  
28

1 been recalled, and as far as the Relators know, all such drug product remains in  
2 commerce.

- 3 163. In addition, a Commercial Change Implementation Plan request (called "*Reprocessing of*  
4 *FTC (ICN-056) at Gilead Alberta to Become ICN-074*") associated with the above  
5 sorting, sieving, contaminate classification activities, defect culling and Master Batch  
6 Record modification, was still unapproved and incomplete in July 2012—months after  
7 the first of the commercial drugs using the adulterated API were placed into commerce.  
8

9 [REDACTED]  
10 Moreover, reprocessing is defined as "Introducing an  
11 intermediate or API, including one that does not conform to standards or specifications,  
12 back into the process and reprocessing by repeating a crystallization step or other  
13 appropriate chemical or physical manipulation steps (e.g., distillation, filtration,  
14 chromatography, milling) that are part of *the established manufacturing process* is  
15 generally considered acceptable." (ICH Q7A Section 14.2) In Gilead's own admission,  
16 Plant 203 did not yield *one* lot of FTC API that was deemed acceptable. The activities  
17 undertaken by the company much more closely align with "Rework." Reworking API  
18 due to gross contamination and that to include Process Validation batches, without FDA  
19 concurrence would have been found to be unacceptable by the GMP's. In spite of the  
20 fact, the company reprocessed [REDACTED] lots of contaminated FTC API [REDACTED]  
21 [REDACTED]  
22 from a supplier whose process validation batches were shown by the FDA to be  
23 adulterated and reassigned them identification numbers to give the appearance that they  
24  
25  
26  
27  
28

1 originated at the Gilead Alberta facility rather than the Synthetics China location under  
2 scrutiny. [REDACTED]

3 164. These events and the [REDACTED] documents provide further evidence of the lack of change  
4 management controls and release-at-all-costs-and-despite-all-risks mentality at Gilead.  
5 No recalls despite known impurities. Post-manufacture sieving of API as a means of  
6 "controlling" contamination. Failure to complete validation of new facilities and change  
7 management controls in a manner suitable for cGMP. [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22  
23  
24

25 <sup>6</sup> The new Synthetics China facility also appears to have been validated improperly. Gilead again used a CBE-30 application  
26 to seek FDA approval of the new facility and [REDACTED] while concurrently moving  
27 manufacturing to a new building within the Synthetics China compound, [REDACTED]  
28 [REDACTED]

1 165. The scope of the issue, isolated internally to those API and drug product lots identified  
2 through investigation, is indeed much broader than the nine batches identified in the  
3 Matzinger email and the November 24<sup>th</sup> report. Tainted API lots were used in the  
4 manufacture of the Synthetics China FTC API process validation batches and the  
5 Truvada process validation batches.  
6

7 166. As such, the impact of the contamination may extend to *all* batches of *all* FTC-based  
8 Gilead drugs which used the ICN-056 API, inclusive of but not limited to the Truvada  
9 and Atripla lots identified in the report. With some [REDACTED] batches implicated, not just the  
10 nine on the original list, the amount of impacted product is staggering.  
11

12 (c.) The FDA Issues a FDA-483 Letter to Gilead  
13

14 167. On June 15, 2012, the FDA performed an inspection of Gilead's Foster City facility as  
15 part of its review of Gilead's application for approval of its new AIDS drug, referred to as  
16 "Quad" (which, after FDA approval, Gilead is now calling "Stribild").  
17

18 168. In addition to reviewing content from the Quad filing, the FDA inspector (Pete Baker, an  
19 FDA Consumer Safety Officer out of Alameda, California) evaluated specifics relating to  
20 a recent FDA field alert filed by Gilead about foreign matter in commercially-distributed  
21 Truvada and Atripla from the ICN-056 API manufactured at Synthetics China's plant  
22 203. He inquired as to the rationale for the company not initiating a recall due to the  
23 contamination and requested that the company state the monetary value of each batch of  
24 product in question.  
25  
26  
27  
28

1 169. In its July 15, 2012 FDA-483 issued to Gilead [REDACTED] the FDA made seven  
2 observations that the investigator believed demonstrated deviation from current Good  
3 Manufacturing Practices ("cGMPs").

4  
5 170. The first observation related to the commercial use of contaminated Synthetics China  
6 FTC in four U.S. commercial, process validation lots of the Gilead drugs Truvada and  
7 Atripla. While Gilead issued an FDA field alert, it failed to recall any of the product  
8 containing foreign matter, a failure specifically noted by the investigator. Per the FDA-  
9 483, two drug product lots were investigated by the company. However, in reality, a  
10 report generated eight months before the issuance of the 483 observation confirmed that  
11 contaminated API (184) was also used in the manufacture of two remaining U.S. finished  
12 products lots. Accordingly, all three FTC Process Validation lots—in addition to three  
13 Truvada and one Atripla Process Validation lots were impacted through the use of the  
14 contaminated API. [REDACTED]

15  
16  
17  
18 171. The remaining observations in the FDA-483 issued to Gilead related to the lack of  
19 integrity of testing results and attributes of commercial product.

20 172. Relator Sherilyn Campie attended several internal meetings at Gilead regarding the FDA-  
21 483, and was thus made aware of its contents.

22  
23 173. Gilead issued a lengthy (over 300 pages) response to the FDA-483 warning letter.  
24 Numerous inaccuracies were contained in the document which was signed off by John  
25 Milligan, Gilead's President. One such statement (concerning why a recall was not  
26 undertaken) is especially disturbing - "if such a recall caused patients to miss one or more  
27  
28

1 doses of their medication due to uncertainty over its safety, patients could experience  
 2 viral rebound or mutation. Gilead thus determined that patient health was best served by  
 3 not recalling the limited amount of product already in the market.” [REDACTED]

4 [REDACTED] While a recall might be inconvenient and expensive for Defendant, the regulations  
 5 require that the product be removed from the marketplace. Unbeknowst to the FDA, the  
 6 company has actively maintained robust inventory stockpiles of both Atripla and  
 7 Truvada. [REDACTED]  
 8 [REDACTED]

9 [REDACTED] As such, the company could have used surplus inventory to replace the  
 10 contaminated drugs which had incorporated the Synthetics China FTC API. [REDACTED]  
 11 [REDACTED]  
 12 [REDACTED]  
 13 [REDACTED]  
 14 [REDACTED]

15 “All FTC lots (identified as Gilead part number ICN-056) manufacturing at Synthetics  
 16 China Building 203 were placed on QA Hold and rejected....” [REDACTED]  
 17 [REDACTED]

18 174. All of Gilead's and Synthetics China's COA's for its drugs that incorporate FTC  
 19 manufactured at Synthetics China Plant 203 contained false statements and material  
 20 omissions, in that they stated that the API was in compliance with cGMP and  
 21 manufactured according to specifications in the NDA, yet Gilead knew that the FTC  
 22 contained contaminations no later than November 2011.  
 23 [REDACTED]

24 175. If the FDA had known about the false statements and material omissions, or if it had  
 25 known that the drugs incorporating FTC manufactured at Plant 203 had these impurities,  
 26 [REDACTED]  
 27 [REDACTED]  
 28 [REDACTED]

1 it would not have granted approval of the use of Plant 203, or would have withdrawn  
2 approval once it learned of them. 21 U.S.C. § 355(e)(5).

3 176. All claims presented to the federal and state governments for drugs manufactured from  
4 API manufactured at Synthetics China's new facility constitute false claims for  
5 unapproved or fraudulently-approved drug productions in violation of the false claims act  
6 and similar state statutes.

7  
8 177. All batches of FTC manufactured at the facility were contaminated and were thus  
9 unapproved for sale in interstate commerce.

10  
11 178. The presence of these unapproved contaminants renders these drugs "adulterated," as  
12 defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the  
13 sale of the adulterated and misbranded drugs constitutes a violation of the false claims act  
14 and similar state statutes.

15  
16 **B. GILEAD DRUGS MANUFACTURED WITH TDF CONTAINED BLACK**  
17 **SPECKS AND OTHER UNDISCLOSED CONTAMINATION FROM TIME**  
18 **OF GILEAD'S NDAS FOR THESE PRODUCTS**

19 179. In April 2001, Gilead submitted a NDA to the FDA for approval of Viread tablets, a drug  
20 used to treat HIV-1 and Chronic Hepatitis-B infections. The FDA approved Viread  
21 tablets for commercial sale and clinical use on October 26, 2001.

22  
23 180. During the time the NDA for Viread tablets was pending, Gilead knew about and was  
24 actively investigating visible black particles discovered in numerous batches of Viread  
25 tablets manufactured at Patheon. [REDACTED]  
26  
27  
28

1 [REDACTED] The black particles were found in the very batches of tablets that  
2 Gilead used to validate its NDA submission for the drug.

3 181. The black particles evidenced clear adulteration and contamination. In its NDA for  
4 Viread tablets, Gilead listed the active ingredient tenofovir disoproxil fumarate ("TDF")  
5 and identified the various inactive ingredients in Viread tablets. None of these materials  
6 is black, and the combination of ingredients was inconsistent with the appearance of  
7 black particles. In fact, Gilead described TDF as a "white to off-white crystalline  
8 powder," a description the FDA adopted in its eventual approval for Viread tablets.  
9 [REDACTED]

10  
11 [REDACTED]  
12 182. Accordingly, prior to FDA approval, Gilead knew that the very Viread tablets that  
13 formed the basis for its NDA contained visible black specks that were foreign to the  
14 listed ingredients. Gilead relied on these batches to validate the statements to the FDA  
15 that TDF could be made with consistent quality and purity, yet did not disclose the  
16 discovery of the black specks.  
17

18  
19 183. Gilead falsely certified the validation batches as having complied with the specifications  
20 in the NDA, when it knew they did not.

21  
22 184. Moreover, Gilead eventually sold the Viread tablets made from the validation lots into  
23 the commercial market without ever disclosing the existence of the black particles or the  
24 fact that the tablets were contaminated.  
25  
26  
27  
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1 185. Through various tests detailed below, Gilead eventually learned that the visible black  
2 specks consist of teflon, charred TDF, acetaminophen, metal shavings, and other  
3 materials not listed in the NDA or any supplement.

4 186. Gilead never disclosed these adulterants to the FDA as additional "ingredients" of TDF or  
5 Viread tablets. If Gilead had disclosed the presence of visible black particles to the FDA,  
6 either in its NDA or a supplement thereto, the FDA would not have approved Viread  
7 tablets, or would have withdrawn approval.  
8

9 187. Similarly, given that Gilead used the same batches of TDF to make Truvada and Atripla  
10 in connection with the NDAs submitted for these drugs, these NDAs were also infected  
11 by the same false statements and omissions. Gilead never disclosed the black specks in  
12 the TDF used to manufacture Truvada and Atripla validation batches either. If Gilead  
13 had disclosed the presence of visible black particles to the FDA, either in its NDA or a  
14 supplement thereto, the FDA would not have approved Truvada or Atripla, or would have  
15 withdrawn approval. (as described above, the other API in these drug products – FTC –  
16 was also tainted by contamination from the time of their respective NDAs, which Gilead  
17 also knew and concealed from the FDA.)  
18

19 188. Internally, Gilead concluded that the black particles were merely "aesthetic defects" that  
20 had no health or safety consequences, thus justifying its decision not to disclose them to  
21 the government or to list them as "ingredients" in the NDAs or any supplements.  
22

23 189. [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 190. In a November 21, 2008 report, a CMO (Nycomed) determined that two TDF batches  
8 that had been or would be incorporated into batches of Truvada were contaminated with  
9 what were most likely metal shavings. [REDACTED]  
10

11 191. After seeing this report, Relator Jeff Campie requested that an independent forensic lab  
12 analyze samples from eight batches of commercial Viread and Truvada tablets, each  
13 sample containing a single dark-colored particle partially embedded within the surface of  
14 the tablet. Gilead refused Mr. Campie's request to have samples of the underlying TDF  
15 API tested at the independent lab as well.  
16

17 [REDACTED]  
18 192. [REDACTED]  
19 [REDACTED] All of the particles isolated from the Viread tablets  
20 were identified as steel swarf. One particle isolated from the Truvada batches was  
21 identified as steel wire, while other particles were composed of chromium nickel,  
22 stainless steel, titanium, chromium, iron, and cobalt. None of these materials is a listed  
23 ingredient in Viread or Truvada tablets.  
24

25 193. Notwithstanding the identification of specific foreign materials in these final drug  
26 products, and despite an internal report stating that significantly higher numbers of tablets  
27  
28

1 of Viread batches were being rejected than normally allowed [REDACTED] Gilead decided  
2 that the occurrence of the black particles "was at a low frequency" and thus acceptable as  
3 "aesthetic defects." Labeling visible contamination such as the black particles as an  
4 "aesthetic defect" is false and fraudulent. Indeed, in a July 22, 2003 FDA Warning Letter  
5 to a different pharmaceutical manufacturer, the FDA, in "disagree[ing] with [the  
6 manufacturer's] position that the presence of black specs is primarily an aesthetic issue,"  
7 stated that "[i]t is not acceptable to have visually observable contaminants in your  
8 finished dosage form products." [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]

12 194. On September 21<sup>st</sup>, 2010, the FDA agreed with Mr. Campie's concern's (regarding the  
13 presence of visible contaminants in the company's drugs). The FDA's position was stated  
14 within the context of a Warning Letter issued to the Gilead, San Dimas California  
15 facility. [REDACTED]  
16 [REDACTED]  
17 [REDACTED]

18 195. All of Gilead's NDAs for its drugs that incorporate TDF contained false statements and  
19 material omissions, in that they listed ingredients that did not include the black specks  
20 discovered no later than 2001. These false statements and material omissions were  
21 intentional, as Gilead knew about the impurities at the time of the NDAs.  
22

23 196. Gilead never submitted supplemental NDAs in order to obtain FDA approval for the  
24 inclusion of the contaminants in its final drug products.  
25

26 197. If the FDA had known about the false statements and material omissions, or if had known  
27 that the drugs incorporating TDF had these impurities, it would not have granted approval  
28

of the new drugs, or would have withdrawn approval once it learned of them. 21 U.S.C. § 355(e)(5).

198. Gilead knew this to be true, which is why it decided not to disclose the impurities and contaminations to the government in its NDAs or in any subsequent disclosures.

199. All claims presented to the federal and state governments for these drugs constitute false claims for unapproved or fraudulently-approved drug productions in violation of the false claims act and similar state statutes.

200. All batches of Viread, Emtriva, or Truvada manufactured with these contaminants were unapproved for sale in interstate commerce.

201. The presence of these unapproved contaminants renders these drugs "adulterated," as defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the sale of the adulterated and misbranded drugs constitutes a violation of the false claims act and similar state statutes.

**C. API AND FINISHED DRUG PRODUCT FOR COMMERCIAL SALE  
ROUTINELY SUBJECTED TO EXTREME TEMPERATURE  
EXCURSIONS THAT CAUSE VISIBLE BUT UNREPORTED  
ADULTERATIONS.**

202. From approximately September 2006 through July 2009, Gilead also knew that API and various drug products, including Viread, Truvada, Hepsera, and Atripla, were routinely subjected to temperature and humidity extremes which rendered the materials adulterated and contaminated for an independent reason beyond the process-related contaminations described above.

1 203. [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]

10 204. All of the drugs manufactured with FTC and TDF API – indeed, all of the drugs at issue  
11 in this amended complaint – are required to be stored at 25C, with permitted "excursions"  
12 within the range of 15C to 30C. [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]

16 205. After reviewing the results of the shipping study, Relator Jeff Campie mandated that all  
17 bulk tablet shipments into Gilead's San Dimas facility – which received shipments from  
18 various CMOs and from which virtually all Gilead sales of bulk tablets to the United  
19 States market originated during this time period – be accompanied by temperature-  
20 recording devices for the ensuing 13-month period. Mr. Campie further mandated that all  
21 bulk tablet drums that experienced excursions outside the permitted temperature range  
22 during the 13-month study be retested for potency and purity prior to determining their  
23 suitability for commercial release. Mr. Campie's intent was two-fold: (1) to ensure  
24 ongoing compliance with approved environmental conditions for Gilead's drug product  
25  
26  
27  
28

1 by requiring the review of in-transit conditions; and (2) to ensure that no drug product  
2 subjected to environmental excursions would be released for packaging and into the  
3 market without first testing for the impact of any such excursions on potency and purity.  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]

7 206. During the [REDACTED] months of the study, the temperature monitors that accompanied [REDACTED]  
8 shipments of drug product showed that [REDACTED] of them (55% overall) had excursions outside  
9 of the permitted range. These [REDACTED] shipments represented all *known* bulk tablet shipments  
10 packaged by Gilead for commercial sale in the United States, including to federal and  
11 state governments, during this time period. [REDACTED]  
12 [REDACTED]  
13 [REDACTED]

14 207. Unbeknownst to Mr. Campie, however, senior management at Gilead overrode and  
15 modified the second of Mr. Campie's conditions for testing. Instead of testing drums that  
16 had been subjected to temperature excursions for potency and purity prior to further  
17 packaging and sale, Gilead continued to release tablets adulterated during transit by  
18 temperature abuse without confirming or even testing for potency and purity. Indeed, the  
19 results of the study – showing that more than half of all shipments had temperature  
20 excursions – were not even reviewed or released until after packaging, sale and final  
21 delivery of finished drug product from the san dimas facility, when of course it was too  
22 late to conduct the further testing mandated by Mr. Campie. During this time, Mr.  
23 Campie was assured by senior management at Gilead that potency and purity testing on  
24 all drums subjected to excursions was being completed, when in fact it was not.  
25  
26  
27  
28

1 208. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 209. Under FDA rules, any incident where a product introduced into commerce is found to

6 have been subjected to conditions outside of what is claimed on the label must be

7 reported to the FDA within 72 hours. At the same time, the manufacturer must develop a

8 recall strategy approved by the FDA to track and segregate all adulterated drug products

9 for destruction.

10

11 210. [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 211. [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED] As such, drug substances compromised by chemical

23 contamination during manufacture or adverse environmental (temperature/humidity)

24 conditions during shipment to the site of tablet manufacture may be incorporated into

25 batches undetected. [REDACTED]

26 [REDACTED]

27 [REDACTED]

28

report (Q106-003). The lot was subsequently released for use in commercial Emtriva capsules—only to be unceremoniously rejected and removed from the stability program due to failing results. [REDACTED]

212. Notwithstanding these rules and its internal protocol, Gilead never tested the batches subjected to extreme temperatures for potency or purity; never placed any of the batches into the stability program; did not possess any stability data to support extreme temperature excursions; never filed the required NDA field alerts; and never recalled any of the shipments.

213. These failures were particularly glaring given that the exposed shipments actually manifested significant contamination and adulteration from the extreme excursions to which they were subjected. Gilead received or noted scores of complaints about broken, moist, melted, and/or fused drug products, as well as noticeable odors [REDACTED] including the following:

A. "moist" Viread tablets [REDACTED] from GSL GS-CUS-00230 and GS-CUS-00237);

B. water found within a bottle of Atripla with tablets sticking together [REDACTED] from GS-CUS-00392;

C. "fused/melted" Hepsera tablets [REDACTED] from TEP055/GS-CUS-00479 Patheon DR 9510;

D. eight "product odor" complaints from Hepsera tablets [REDACTED]

[REDACTED]

E. at least 45 complaints about "broken/chipped Hepsera tablets" over 12 months

██████████ GS-CUS-00477;

214. All approved drugs must be manufactured in accordance with FDA-approved manufacturing processes, in-process controls, and specifications established by NDAs. The applicant must notify the FDA about any changes to any condition in the approved NDA. 21 C.F.R. § 314.70(a)(1)(i). Exposure to extreme temperatures outside of the approved temperature range, particularly excursions extreme enough to melt, break, fuse and deform tablets, represent a "change" that must be reported to the FDA.

215. If the applicant makes or learns of any change from the FDA-approved NDA, it is forbidden from distributing any drug product containing the change until it has filed a supplemental application with the FDA and received FDA approval for the change. 21 C.F.R. § 315.70(b)(2).

216. Accordingly, before Gilead could lawfully sell drug products exposed to extreme temperatures, they had to seek and obtain FDA approval. Yet Defendant failed to disclose the excursions to the FDA, let alone to seek and obtain FDA approval for sale.

217. All claims presented to the federal and state governments for these drugs constitute false claims for unapproved or fraudulently-approved drug productions in violation of the false claims act and similar state statutes.

218. All batches of Emtriva, Viread, Hepsera, Truvada, Atripla, Complera, and Stribild that were subjected to these temperature excursions and were thus adulterated were unapproved for sale in interstate commerce.

1 219. The presence of these unapproved contaminants renders these drugs "adulterated," as  
2 defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the  
3 sale of the adulterated and misbranded drugs constitutes a violation of the false claims act  
4 and similar state statutes.

5  
6 **D. COMMERCIAL BATCHES OF "CAYSTON," AN INHALED DRUG TO**  
7 **TREAT CYSTIC FIBROSIS, HAVE BEEN MANUFACTURED AND**  
8 **DISTRIBUTED WITH API KNOWN TO CONTAIN METAL**  
9 **PARTICULATES**

10 220. Aztreonam is the API utilized in the manufacture of Gilead's FDA-approved "Cayston"  
11 (also known as "AZLI"), an inhaled drug prescribed for those suffering from Cystic  
12 Fibrosis (CF) for ages 7 and older.

13 221. The typical and progressively-debilitating characteristics of the CF disease include  
14 chronic inflammation of the lungs and sinus and infection and structural changes to the  
15 respiratory tract, and lead to a variety of symptoms. In later stages, changes in the  
16 architecture of the lung such as pathology in the major airways further exacerbate  
17 difficulties in breathing. Other symptoms include coughing up blood, high blood pressure  
18 in the lung (pulmonary hypertension), heart failure, difficulties getting enough oxygen to  
19 the body, and respiratory failure requiring support with breathing masks.  
20 Cardiorespiratory complications are the most common cause of death (approximately  
21 80%) in patients.

22 222. [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4  
5 223. Gilead never submitted a supplemental NDA in order to obtain FDA approval for the  
6 inclusion of the known contaminants in Cayston; never issued an FDA field alert or  
7 initiated recall activities; and never disclosed the contaminants to the FDA.

8  
9 224. More recently, in December 2012 and again in July 2013, two consecutive FDA  
10 inspections Cayston manufacturing (at a contract manufacturing organization) have  
11 yielded predictable, repeat, and alarming, 483 observations regarding black specks  
12 consisting, minimally, of stainless steel, charred organic material (undetermined origin),  
13 cellulose, charred protein, polyester resin or an alkyd paint/coating, wood fibers, metal  
14 shavings (iron alloy) in approximately 18 batches of Cayston drug product. [REDACTED]

15  
16 [REDACTED] Long-standing FDA compliance and enforcement activities are replete with  
17 enforcement actions taken against contamination in such drugs (i.e. drugs purported to be  
18 sterile). [REDACTED]  
19

20 225. All claims presented to the federal and state governments for Cayston manufactured with  
21 these contaminants constitute false claims for unapproved or fraudulently-approved drug  
22 productions in violation of the false claims act and similar state statutes.  
23

24 226. All batches of Cayston manufactured with these contaminants were unapproved for sale  
25 in interstate commerce.  
26  
27  
28

227. The presence of these unapproved contaminants renders these drugs "adulterated," as defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the sale of the adulterated and misbranded drugs constitutes a violation of the false claims act and similar state statutes.

**E. PRODUCT MIX-UP, CONTAMINATION ISSUES AND OTHER GMP ISSUES INVOLVING COMMERCIAL DRUG PRODUCTS**

228. In addition to the above examples, the defendants have allowed finished drug product to be sold commercially despite known defects and adulterations, and have failed to properly report these issues to the FDA or to recall the adulterated product.

**(1) Product Mix-Up ("Comingling")**

229. On a reoccurring basis, various company functions have been notified by Medical personnel and patients that product mix-ups have occurred with Gilead drugs. In each event, company management directed that no notification be forthcoming to the agency and that no potential recall actions be undertaken. As such, on August 3, 2006, a patient notified the company that the Viread tablets he received were white instead of the (FDA) approved blue tablets. Test results confirmed the tablets to be Lamivudine. [REDACTED] Next, on August 31, 2006, a patient notified the company after finding orange pills inside a bottle of Truvada tablets. The tablets were later identified by a pharmacist as Kaletra (a GSK drug). [REDACTED] Also, on August 31, 2006, a pharmacy reported finding Viread Tablets inside a Truvada bottle. [REDACTED] In early October of 2006, a customer reported that he received a bottle of Viread tablets which contained white/orange capsules rather than FDA-approved blue Viread tablets. [REDACTED] On

1 January 31, 2008, the company registered a customer complaint involving a bottle of  
2 Atripla tablets containing white tablets and yellow-orange caplets. [REDACTED] In March  
3 2008 a customer complaint record (GS-CUS-00423) was generated when a bottle of  
4 Atripla tablets was found to contain Truvada tablets. [REDACTED] On November 12,  
5 2008, a nurse practitioner notified Gilead that an adverse event had been associated with  
6 a patient who, presumably, ingested white tablets found within a sealed bottle of Atripla  
7 tablets. [REDACTED] On May 13, 2009, there was a report from Germany of a sealed  
8 Truvada bottle containing unidentified white tablets [REDACTED] and again on May 29,  
9 2009, when a bottle of Truvada tablets was found to contain foreign capsules in it. [REDACTED]  
10 [REDACTED] On another occasion, on April 23, 2009, Relator Jeff Campie's  
11 department at Gilead (Commercial Quality) was alerted to the fact that San Dimas had  
12 been notified of a discovery by a pharmacist of a Truvada tablet that had been found  
13 inside a sealed bottle of Viread tablets. [REDACTED] The Truvada tablet was coated in  
14 the color associated with FDA-approved Viread tablets. [REDACTED]

15  
16  
17  
18  
19 230. Mr. Campie requested that the complaint sample be sent to Gilead's Foster City facility  
20 for analysis by the product development management function, which confirmed the  
21 initial report. [REDACTED] He was also critiqued by his manager for requiring that the  
22 testing of the complaint sample be undertaken via protocol. [REDACTED] Nonetheless,  
23 Mr. Campie copied senior management on all relevant correspondence [REDACTED]  
24 [REDACTED] and presented the findings, including photographs and test results, to a team of  
25 Gilead senior management, consisting of Senior Presidents/Vice Presidents Tony  
26  
27  
28

1 Caracciolo, Taiyin Yang, David Pizzutti and Chief Compliance Officer Ron Branning.  
 2 Mr. Campie stated that the incident was an event requiring a field alert and a recall of the  
 3 drug products involved. Mr. Campie did not have the authority to order recalls or  
 4 suspension of manufacturing or shipment of product, or to report regulatory concerns to  
 5 the FDA. All he could do was urge Gilead management to take these actions, which he  
 6 did. They failed to do so.  
 7

8  
 9 231. On June 5, 2009, David Pizzutti, Gilead's Vice President of Regulatory Affairs, signed  
 10 off on a certification contained within an FDA field alert relating to the comingling event.  
 11 The FDA field alert falsely stated, among other things, that the mix-up complaint had  
 12 never been confirmed. [REDACTED] Gilead never initiated a recall of the impacted  
 13 product although it was required to do so.  
 14

15 232. After Gilead issued the field alert, Tony Caracciolo, to whom Mr. Campie reported,  
 16 reprimanded Mr. Campie for relaying to Gilead management that the comingling incident  
 17 was a recallable event, stating that this evidenced that Mr. Campie was of little use to the  
 18 company and that Mr. Campie's "heart wasn't in the job anymore."  
 19

20 233. The May 2009 Product Complaints Summary Report [REDACTED] contained several of  
 21 the above-referenced mix-ups and was distributed to senior Gilead management to  
 22 include the company's Chief Compliance Officer (R. Branning).  
 23

## 24 (2) Additional Instances of Contaminated Drug Product

25

26 234. Microbial contamination in Hepsera tablet lot. In 2009, after Mr. Campie had tried  
 27 unsuccessfully for months to have the batch destroyed, Gilead dispositioned and released  
 28

1 into commerce a Hepsera tablet lot confirmed to be microbially contaminated by  
2 pseudomonas aeruginosa ("p. aeruginosa"). [REDACTED] Mortality from *p. Aeruginosa*  
3 infections in HIV-positive patients is estimated to be 22% to 36%. See "changing  
4 epidemiology of pseudomonas aeruginosa in HIV-infected patients," Marjorie P. Golden,  
5 MD, Hospital of Saint Raphael and Yale University School of Medicine, New Haven,  
6 Conn., Sue J. Goldie, MD, Harvard University School of Public Health, Boston (Feb 01,  
7 2000). Yet Gilead somehow justified release of the contaminated lot to this immuno-  
8 compromised population.  
9

10  
11 235. **Truvada tablets contaminated by blood.** In June 2008, Gilead reimported and  
12 "reclaimed" a lot of Truvada tablets for distribution in the United States even though the  
13 same lot, FCF065, was previously rejected by the Japanese CMO for being contaminated  
14 with blood, burnt packing, and faulty induction seals. [REDACTED]  
15 [REDACTED]  
16 [REDACTED]

17  
18 236. **Metal found in Hepsera tablets.** In an October 22, 2004 memo, Patheon confirmed  
19 verbal notification from Gilead of a complaint relating to the discovery of extraneous  
20 material specified as aluminum alloy in two Hepsera tablets. [REDACTED]  
21

22 237. But summarizing Gilead's instructions, the Patheon memo went on to state that since "the  
23 size of the material was below the detection limits of the metal detector, no further action  
24 will be taken at this time."  
25  
26  
27  
28

238. Once again, Gilead ignored a known contamination on a flimsy technicality—justifying “no further action” simply because the aluminum shards were too small to be detected by ordinary means.

239. **Contaminated/Defective Sterile Drugs.** Multiple physician complaints warranting FDA field alerts and recall activities were received by the company for the sterile (injectable) drug Macugen, a drug intended for the treatment of macular degeneration. Among the complaints were issues were dull and bent needles, “floaters” in patients’ eyes, silicone bubbles in patients’ eyes and needle tips contaminated with glue. No FDA notification, field alerts, or recalls were initiated. [REDACTED]

240. **Lack of bioequivalence.** Tablets registered under a single Gilead NDA, for example Truvada, are manufactured, with varying orders of addition of the ingredients, from one Gilead CMO site to the next Gilead site of manufacture. As such, there is no linkage between the tableted production in commerce and the initial batches manufactured to demonstrate bioequivalence that formed the basis of FDA approval in the first place.

241. **Lack of Analytical Method Validation.** Analytical test methods are required to be validated prior to being utilized to evaluate FDA registration batches. [REDACTED]

[REDACTED] As a result of Relator Jeff Campie’s concerns involving the lack of such adherence by the company, an external audit was undertaken of the Gilead PDM laboratory in June 2008. [REDACTED]

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4  
5 242. **Lack of (Manufacturing) Process Validation.** Validation of manufacturing processes  
6 is a requirement of the cGMP regulations. As such, processes are required to be  
7 validated prior to placing commercial drug (from such processes) into interstate  
8 commerce. [REDACTED] In late 2006/early 2007, in the midst of repeated Atripla tablet  
9 batch excursions, Relator Jeff Campie requested the Analytical Method validation  
10 package for Atripla tablets. While reviewing the validation report, it became apparent  
11 that the validation exercise had failed to meet the acceptance criteria for drug potency and  
12 content uniformity as he noticed that, among the numerous deviations (failures) which  
13 had occurred, one associated with "extraction time" had also taken place. [REDACTED]  
14 [REDACTED]  
15 [REDACTED] When Mr. Campie asked a Senior Director (T. Weber) if anyone (a  
16 regulator) had ever reviewed the report, he was told "they (the FDA) could have looked  
17 at it if they had wanted to."  
18  
19

20 243. In a second event, defective Process Validation lots for Viread Tablets [REDACTED]  
21 manufactured in Germany for the U.S. marketplace were mandated under the direction of  
22 a senior vice president and Relator Jeff Campie's manager, Tony Caracciolo. [REDACTED]  
23 [REDACTED] to be shipped from Germany, culled out in San Dimas and placed into U.S.  
24 commerce for sale. The event (lack of validation) was subsequently deemed violative  
25 and was contained within an FDA Warning Letter issued to Gilead Science (San Dimas)  
26  
27  
28

1 in 2010. [REDACTED] To insulate the company from further scrutiny, the company  
 2 decided to remove the defective, yet marketed lots from the stability program. [REDACTED]  
 3 [REDACTED]

4  
 5 **F. CONTAMINATION AND ADULTERATION IN CLINICAL DRUG**  
 6 **PRODUCTS, INCLUDING PRODUCTS LATER APPROVED FOR**  
 7 **COMMERCIAL SALE**

8 244. There is a common thread to many of Gilead's schemes, most of which have been  
 9 operational and refined over multiple years. The following are significant examples of  
 10 the same pattern of poor GMP and contaminated and adulterated API and drug product as  
 11 detailed above, but in clinical trial drug settings.

12 245. Gilead relies on clinical trials to gain approval for new drugs and formulations.  
 13 Accordingly, its pattern and practice of concealing significant issues with the purity and  
 14 potency of API and finished drug product reflects the same desire described above to  
 15 maximize profit at the expense of highly vulnerable patients and test subjects.  
 16

17 246. The clinical trial drugs discussed below are in the process of approval, or have already  
 18 been approved, by the FDA, without defendants ever disclosing material deficiencies and  
 19 contaminations in the API and drug product, and having concealed any link between  
 20 these undisclosed issues and "adverse events" in the test population that may have been  
 21 caused by them. Accordingly, all claims presented to the federal and state governments  
 22 for these drugs constitute false claims for unapproved or fraudulently-approved drug  
 23 productions in violation of the false claims act and similar state statutes.  
 24

25  
 26 247. In addition, the federal government sponsored and/or funded the drug trials involving  
 27 these undisclosed, tainted products. Gilead was required to identify and disclose any new  
 28

1 or known impurity or degradants in the API supplied to these studies. Yet Gilead failed  
2 to disclose the known impurities and degradants identified below. Each such failure also  
3 constitutes a violation of the false claims act and similar state statutes.

4  
5 **G. UNDISCLOSED CONTAMINATION DISCOVERED DURING**  
6 **PEDIATRIC CLINICAL STUDIES FOR VIREAD**

7 248. Gilead was required by terms contained in the FDA approval letter for Viread tablets to  
8 develop and conduct clinical trials in the pediatric population afflicted with HIV using  
9 the API TDF contained in the solid-dose, tablet form of its Viread drug.

10  
11 249. If successful in gaining FDA approval for the pediatric formulation, the company would  
12 realize a six (6) month extension to patent(s) associated with the TDF molecule and  
13 realize an estimated \$3 billion in additional revenues.

14  
15 250. In various trials, beginning no later than 2002 to the present, Gilead knowingly provided  
16 the trial participants – newborns through age 18 - with both TDF Oral Suspension and  
17 TDF Oral Powder that contained black particles, foreign matter, gross contamination, and  
18 visible filth – all from unknown origin. Nevertheless, Gilead failed to report any of this  
19 to the government, instead certifying the results of multiple studies to the FDA.  
20  
21  
22  
23  
24  
25  
26  
27  
28

EVANS LAW FIRM, INC.

**(3) Black and Brown Specks in Oral Suspension & Oral Powder**

251. From the very beginning of its efforts to develop a pediatric formulation, Gilead and its API manufacturers and CMOs were unable to rid the product of black and brown specks representing contaminants from the manufacturing process.

252. In November 2002, Gilead's CMO, Patheon, identified the issue in several lots of TDF (the API in the oral suspension formulation), and Gilead opened an investigation into the issue. [REDACTED]

253. In the meantime, by March 2005, Gilead was issuing technical reports to support its filing for post-market approval with the FDA that failed to mention the black and brown speck issues, and stating that the finished lots "met all acceptance criteria." [REDACTED]

254. Shortly thereafter, Gilead instructed the contract manufacturer to stop even looking for the contamination, as if the problem would disappear simply by shutting their eyes to it - [REDACTED]

1 255. The expiration dates on lots of finished product were extended for months and years  
2 without any evidence of follow-up testing or examination of the lots for contamination.  
3 [REDACTED]

4  
5 256. It soon became apparent that the problem was not going away. There were several  
6 ongoing clinical studies at the time in various phases, many with issues of contaminated  
7 drug product.

8  
9 257. For example, the phase III study, entitled "Safety and Efficacy of Switching from  
10 Stavudine or Zidovudine to Tenofovir DF in HIV-1 infected children (ages 2-<12),"  
11 study ID number of GS-US-104-0352, began in approximately January 2007 and had a  
12 primary collection date of February 2009. [REDACTED]

13 [REDACTED]  
14 In its "interim clinical study report" for this study, Gilead listed the  
15 lots of TDF Oral Powder that were being used for the drug product utilized in the study.  
16 The lots included, among others, lot AD0602BR2 ("lot 602BR2"). [REDACTED]

17  
18 258. [REDACTED]  
19 [REDACTED]  
20 original and reblended lots contained "small black and reddish-brown [sic] particles,"  
21 which were observed after shipping the encapsulated API, from Eurand, to the CMO,  
22 Patheon. Gilead's internal quality assurance memo in February 2008 stated that there was  
23 a probable (but not definitive) cause of the black particles related to "PTFE packing  
24 material," - or Teflon. [REDACTED]  
25  
26  
27  
28

1 259. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 260. Yet Gilead knew that the problem had not been solved. [REDACTED]

7 inspection report, Gilead acknowledged that the preventive measures taken by Eurand

8 with regard to its PTFE packing material "did not eliminate specks from appearing," and

9 that the measures were only effective "in eliminating the specks in *some* microcap

10 sublots." [REDACTED]

11 [REDACTED]

12 261. Moreover, Gilead knew that not all of the specks were PTFE or food-grade Teflon. In an

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 concluded that "few of the insoluble dark particles are confirmed as PTFE based material

17 with the remainder without the characteristic PTFE bands." [REDACTED]

18 [REDACTED]

19 262. Within a few months, Eurand was issuing out-of-specification and deviation inspection

20 reports regarding its (encapsulated) TDF API showing that it was contaminated with

21 acetaminophen (sometimes referred to as "APAP"). [REDACTED]

22 [REDACTED]

23 263. APAP is a contaminant in the Viread Oral Powder formulation, but not coincidentally, is

24 a drug substance that Eurand manufactures for another pharmaceutical company, on the

25 very same equipment train with which it manufactures the encapsulated TDF material.

26

27

28

1 264. Eurand acknowledged in a memo dated October 31, 2008 that "brown particles" in its  
2 TDF API were "found to contain acetaminophen." [REDACTED]

3 265. Gilead knew that lot 602BR2 contained black specks which it knew was Teflon and  
4 brown specks that it had reason to believe was acetaminophen. Neither Teflon nor  
5 acetaminophen is an ingredient in Viread tablets or the pediatric oral powder  
6 formulations.  
7

8 266. To mask any additional scrutiny in an effort to gain FDA approval, the company created  
9 multiple specifications: [REDACTED]  
10 [REDACTED]

11 [REDACTED]  
12 [REDACTED] In sum, Gilead allows over  
13 [REDACTED] to be present in an FDA approved drug – without the FDA's  
14 knowledge that the ingredient is present.  
15

#### 16 (4) Contaminated Drug Product Released for Clinical Study

17  
18 267. Despite these impurities – one known, one suspected, both evident even from visual  
19 inspection – Gilead still went forward with release of these lots to the clinical studies of  
20 Viread Oral Powder for pediatric patients.  
21

22 268. [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27  
28

1 [REDACTED]  
2 [REDACTED]  
3 269. The lot was released for human clinical use on July 15, 2008. (Exh. L(18).)

4 270. Again, in its technical report to support its filing for the pediatric formulation and to  
5 obtain the additional 6 months of patent exclusivity for the TDF molecule with the FDA,  
6 Gilead failed to mention anything about the black or brown specks, the Teflon or APAP  
7 contamination, or anything else about the evident problems with its Viread Oral Powder  
8 formulation. [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]

12 271. With the manufacture of registration lots accompanied by ongoing problems—several  
13 slides were presented (at a senior management meeting on the project), [REDACTED]  
14 highlighting the contamination in the pediatric formulation. The slides prompted a senior  
15 director to state: “I just wish we could make a batch that wasn’t contaminated with  
16 acetaminophen.”  
17 [REDACTED]  
18 [REDACTED]

19 272. Subsequently manufactured lots continued to exhibit questionable quality attributes; for  
20 example AD601B1. [REDACTED]  
21 [REDACTED]

22 [REDACTED] Viread Oral Powder, which is  
23 intended for a vulnerable pediatric patient population, is contaminated and degrades too  
24 quickly, yet the company continued forward with its plans to file the product with the  
25 FDA in exchange for a payday estimated at \$3 billion. On January 18, 2012, the NDA  
26 was approved. [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

1 273. Gilead's NDA for Viread Oral Powder contained false statements and material  
2 omissions, in that it listed ingredients that did not include the black and brown specks  
3 discovered no later than 2002. These false statements and material omissions were  
4 intentional, as Gilead knew about the impurities at the time of the NDA.  
5

6 274. Gilead never submitted a supplement to the NDA in order to obtain FDA approval for the  
7 inclusion of the contaminants in its final drug products.  
8

9 275. If the FDA had known about the false statements and material omissions, or if it had  
10 known that Viread Oral Powder had these impurities, it would not have granted approval  
11 of the new drug formulation, or would have withdrawn approval once it learned of them.  
12  
13 21 U.S.C. § 355(e)(5).

14 276. Gilead knew this to be true, which is why it decided not to disclose the impurities and  
15 contaminations to the government in its NDA or in any subsequent disclosures.  
16

17 277. All claims presented to the federal and state governments for Viread Oral Powder  
18 constitute false claims for unapproved or fraudulently-approved drug productions in  
19 violation of the false claims act and similar state statutes.  
20

21 278. All batches of Viread Oral Powder manufactured with these contaminants were  
22 unapproved for sale in interstate commerce.

23 279. The presence of these unapproved contaminants renders these drugs "adulterated," as  
24 defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the  
25 sale of the adulterated and misbranded drugs constitutes a violation of the false claims act  
26 and similar state statutes.  
27  
28

1 280. In addition, the federal government sponsored and/or funded the drug trials involving  
2 these undisclosed, tainted products. Gilead was required to identify and disclose any new  
3 or known impurity or degradants in the API supplied to these studies. Yet Gilead failed  
4 to disclose the known impurities and degradants identified above. Each such failure also  
5 constitutes a violation of the false claims act and similar state statutes.  
6

7 **H. CHILDREN IN PEDIATRIC HEPSERA STUDY DOSED WITH**  
8 **CONTAMINATED PRODUCT**

9 281. Under terms of the FDA approval for Hepsera tablets, Gilead was required to develop a  
10 pediatric formulation of the Hepsera drug product and to conduct clinical trials in an  
11 attempt to combat Hepatitis B in the pediatric population. [REDACTED]  
12 [REDACTED]  
13 [REDACTED]

14  
15 282. In various trials over several years, Gilead knowingly provided the trial participants –  
16 children ages 2-17 – with Hepsera containing API adefovir dipivoxil ("adefovir DP") for  
17 oral suspension that had previously failed internal stability requirements associated with  
18 potency and purity, and placebo (oral suspension) that possessed gross contamination or  
19 "visible filth" from unknown origin.  
20

21 283. The very clinical trial (GS-US-103-0518) which enabled Gilead to enjoy increased sales  
22 through expansion of the patient population for Hepsera from the approved 18-and-older  
23 age group to ages 12 and older, utilized placebo (oral suspension) tainted by cadmium, a  
24 contamination visibly observed by Gilead's CMO, Patheon, during manufacture of the  
25 placebo lot, forensically identified by a third-party laboratory, and classified in Gilead  
26  
27  
28

documents as a "critical" defect. Yet subsequently this placebo was given to study participants.

284. Gilead failed to report any of this to the government, instead certifying the results of the studies to the FDA, and indicating that "there was no issue with the formulation [of the drug]." the FDA approved the application and waived the requirement for the company to perform additional studies. [REDACTED]

285. The Relators believe that the FDA would not have approved the expanded indication for the tablets, and in fact would have halted the study - if it had been told the truth concerning the company's use of a contaminated placebo.

**(5) Oral Suspension Lot Used in Bioequivalency Studies Contained Excessive Impurities**

286. From the very beginning of its efforts to develop a pediatric formulation, Gilead and its API and contract manufacturers were unable to produce a stable product.

287. To demonstrate bioequivalence between the approved Hepsera tablet and the pediatric formulation, the company manufactured adefovir DP for oral suspension lot U201A2 in late September 2002. [REDACTED]

288. The batch was used in two clinical studies (GS-02-515 and GS-02-517). [REDACTED] However, by January 2003, slightly more than [REDACTED] weeks after manufacture of the batch, samples from the lot (U201A2) that had been stored at 25C/60RH were failing for potency [REDACTED] and impurities [REDACTED]. [REDACTED]

1 289. [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED] The events went unreported, and the batch  
7 continued to be used in the clinical study.  
8

9 **(6) Contaminated Placebo Released for Clinical Study**

10 290. Gross contamination comprised of foreign matter was also observed during the  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]

14 291. The batch was being manufactured to support a phase III safety & efficacy study in the  
15 pediatric population afflicted by Hepatitis B and to fulfill a pre-existing condition  
16 associated with the FDA approval for Hepsera tablets. [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19

20 292. By June 2003, Patheon had sent a sample of the placebo to a third-party forensic  
21 laboratory which concluded that the sample contained cadmium – a defect classified by  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]

25 293. By August of 2003, Patheon had opened a quality investigation report associated with the  
26 same Patheon lot number (C0121A001), [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

1 294. Shortly thereafter, despite Patheon's initial observation of foreign matter, and despite  
2 bodycote's forensic determination of cadmium (and other metals) and Gilead's own  
3 classification of the cadmium contamination in the placebo as "critical," thus warranting  
4 rejection and disposal of the batch, Gilead released the placebo to supply the Phase III,  
5 double-blind, safety & efficacy study (GS-US-103-0518) of adefovir DP in a pediatric  
6 population, ages 2-18. [REDACTED]  
7

8 295. In the memo Gilead sent to Patheon in August 2004, the company explained that while  
9 the lot was contaminated, and despite there being "no conclusive evidence to pinpoint the  
10 source of the particle," the contamination was "isolated." [REDACTED]  
11 [REDACTED]  
12

13 296. No explanation is provided in the memo, or elsewhere as far as the Relators know,  
14 justifying the release of the contaminated placebo lot to the children in the study. Nor did  
15 Gilead publish information about the failed lot to the government, which approved  
16 Gilead's supplemental NDA for an expanded prescribing age group (12-17 year olds) for  
17 Hepsera tablets based on the study (GS-103-1518) which utilized the contaminated  
18 supplies in December 2007.  
19

20 297. Gilead's supplemental NDA for Hepsera tablets contained false statements and material  
21 omissions, in that it listed ingredients that did not include the contaminations discovered  
22 no later than 2003. These false statements and material omissions were intentional, as  
23 Gilead knew about the impurities at the time of the supplemental NDA.  
24  
25  
26  
27  
28

1 298. Gilead never submitted a supplement in order to obtain FDA approval for the inclusion of  
2 the contaminants in its final drug products.

3 299. If the FDA had known about the false statements and material omissions, or if had known  
4 that the drugs had these impurities, it would not have granted approval of the new  
5 formulation, or would have withdrawn approval once it learned of them. 21 U.S.C.  
6 § 355(e)(5).  
7

8 300. Gilead knew this to be true, which is why it decided not to disclose the impurities and  
9 contaminations to the government in its NDA or in any subsequent disclosures.  
10

11 301. All claims presented to the federal and state governments for these drugs constitute false  
12 claims for unapproved or fraudulently-approved drug productions in violation of the false  
13 claims act and similar state statutes.  
14

15 302. All batches of Hepsera tablets for the initial patient population and the expanded age  
16 group manufactured with these contaminants were unapproved for sale in interstate  
17 commerce.  
18

19 303. The presence of these unapproved contaminants renders these drugs "adulterated," as  
20 defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the  
21 sale of the adulterated and misbranded drugs constitutes a violation of the false claims act  
22 and similar state statutes.  
23

24 304. In addition, the federal government sponsored and/or funded the drug trials involving  
25 these undisclosed, tainted products. Gilead was required to identify and disclose any new  
26 or known impurity or degradants in the API supplied to these studies. Yet Gilead failed  
27  
28

1 to disclose the known impurities and degradants identified above. Each such failure also  
 2 constitutes a violation of the false claims act and similar state statutes.

3  
 4 **I. GILEAD FAILS TO DISCLOSE CONTAMINATION ISSUES IN NEW**  
 5 **COMBINATION DRUG COMPLERA DESPITE FDA'S DIRECT**  
 6 **REQUESTS FOR INFORMATION**

7 305. On February 10, 2011, Gilead submitted an NDA (NDA 202-123) for a new combination  
 8 drug, "Complera," comprised of the following API's: emtricitabine (FTC), rilpivirine,  
 9 and TDF. On June 2, 2011, the FDA wrote Gilead with comments and information  
 10 requests relating to this NDA. [REDACTED] The FDA's letter was forwarded internally at  
 11 Gilead to Relator Sherilyn Campie.

12 **(7) Gilead Uses FTC of Questionable Quality**

13 306. In the first item under "drug substance," the FDA requests from Gilead batch analyses of  
 14 the API, by lot number, that comprise the pivotal clinical, stability, scale up, and  
 15 commercial batches of the new drug product. The specific lot numbers listed by the FDA  
 16 in the June 2 letter are batches of FTC API used by Gilead in manufacturing the final  
 17 drug product.  
 18

19  
 20 307. Two of the batch numbers (11136091022 and 1136062003) were manufactured at Evonik  
 21 Technochemie GMBH ("Evonik"). The first, lot 1136091022, was manufactured by  
 22 Evonik during 2009, as evidenced by the "09" digits in the middle of the lot number, a  
 23 convention that Evonik (and Gilead) use to distinguish lots by date of manufacture.  
 24

25 308. The Relators believe that this lot may have been among a number of FTC batches  
 26 produced at Evonik in 2009 that were impacted by agglomeration caused by deficient  
 27  
 28

equipment design at one of Evonik's facilities. [REDACTED]

309. [REDACTED]

Gilead determined to [REDACTED] all of the validation batches, but not to conduct any additional development or stability testing or to qualify the [REDACTED]

310. The [REDACTED] of the agglomerated lots appears not to have been successful. A March 23, 2010 memo from Gilead's analytical chemistry group establishes that one of the original validation lots contained "lumps of white solids" comprised of "highly compacted FTC drug substance" with extreme potency. [REDACTED]

311. By that time in 2010, the [REDACTED] of the validation lots likely would have taken place already. If so, then Gilead was aware that agglomeration continued to be a problem with the FTC manufactured by Evonik in 2009, even after [REDACTED]. Again, the specific batch inquired about by the FDA (lot 1136091022) may well have been part of that failed campaign. The Relators do not believe that Gilead informed the FDA about any of these issues in its recent response to the June 2 letter.

312. Moreover, Gilead may be pushing through 2009 Evonik-manufactured FTC, and its attendant agglomeration issues, into final drug products. [REDACTED]

Again,

1 Gilead may be facilitating the use of flawed FTC in final drug products through its odd  
2 use of multiple internal control numbers ("ICNs") for product.

3 313. For example, Gilead used ICN-039 for the flawed, 2009 batches of Evonik ftc. [REDACTED]

4 [REDACTED] Yet batches of this same product were subsequently re-numbered as  
5 "ICN-027," as evidenced by the handwritten changes to these certificates of analysis.

6 [REDACTED] Giving different ICNs to flawed batches is one way that Gilead may be  
7 attempting to insulate the batches from scrutiny, as the paper trail for the flawed ICNs  
8 gives way to "clean" ICN histories with the mere change of numbers.

9  
10  
11 314. The second Evonik batch for which the FDA recently sought "batch analysis results" is  
12 lot 1136062003, a lot manufactured at Evonik in 2006. With respect to this lot, Gilead's  
13 paperwork and batch analysis results are a mess.

14  
15 315. [REDACTED] are two different Gilead COAs for this one lot number. They are  
16 dated roughly six weeks apart (Sept. 1, 2009 and Oct. 15, 2009), and they contain  
17 different analysis result data from one another. The earlier COA from September 2009  
18 indicates that it was the result of a "retest." the later COA from October 2009 reflects  
19 that it is based on further retests at both Gilead Alberta and Evonik, as if the results of  
20 multiple retests were somehow hybridized into a single COA.

21  
22  
23 **(8) Gilead Provides Incomplete, Misleading, and False Information in**  
24 **Response to the FDA's Specific Questions**

25 316. Later in its June 2 letter, the FDA requests information about the impurity content in a  
26 clinical batch of FTC/RPV/TDF tablets with lot number BY1011B. Unbeknownst to the  
27 FDA (both before the letter and apparently even after Gilead's response to it), the stability  
28

1 study on this batch of FTC/RPV/TDF tablets was terminated by Gilead in late 2010 due  
2 to aberrant results in testing.

3 317. [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]

7 318. As such, the batch should have been rejected and the root cause for the excessive strength  
8 results determined prior to commencement of additional lots. Additionally, the  
9 dissolution testing performed at the 3-month stability interval documented RPV strength  
10 ranges between 15% in one tablet to 176% in the next tablet.

11  
12 319. Given the evidence of out-of-control processes for this lot and agglomerative tendencies,  
13 Gilead determined to terminate the stability study and to reject the lot. But Gilead also  
14 concluded (somehow) that "the aberrant results are considered as isolated and not  
15 representative," again consigning the failed result to an isolated instance.

16  
17 320. The Relators do not believe that Gilead, in responding to the FDA's specific information  
18 request about this lot, provided a full and accurate portrayal of the internal investigation  
19 and decision described in the attached documents.

20  
21 321. Gilead's NDA for the new drug contained false statements and material omissions, in that  
22 it listed ingredients that did not include the contaminations discovered no later than 2010.  
23 These false statements and material omissions were intentional, as Gilead knew about the  
24 impurities at the time of the NDA.  
25  
26  
27  
28

1 322. Gilead never submitted a supplemental NDA in order to obtain FDA approval for the  
2 inclusion of the contaminants in its final drug products.

3 323. If the FDA had known about the false statements and material omissions, or if had known  
4 that the drugs had these impurities, it would not have granted approval of the new  
5 formulation, or would have withdrawn approval once it learned of them. 21 U.S.C.  
6 § 355(e)(5).  
7

8 324. Gilead knew this to be true, which is why it decided not to disclose the impurities and  
9 contaminations to the government in its NDA or in any subsequent disclosures.  
10 Complera was approved by the FDA based on these material omissions on August 10,  
11 2011.  
12

13 325. All claims presented to the federal and state governments for Complera constitute false  
14 claims for unapproved or fraudulently-approved drug productions in violation of the false  
15 claims act and similar state statutes.  
16

17 326. All batches of Complera manufactured with these contaminants were unapproved for sale  
18 in interstate commerce.  
19

20 327. The presence of these unapproved contaminants renders Complera "adulterated," as  
21 defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the  
22 sale of the adulterated and misbranded drugs constitutes a violation of the false claims act  
23 and similar state statutes.  
24

25 328. In addition, the federal government sponsored, funded and/or approved the drug trials  
26 involving these undisclosed, tainted products. Gilead was required to identify and  
27  
28

disclose any new or known impurity or degradants in the API supplied to these studies(under 21 C.F.R. 56.108(b)). Yet Gilead failed to disclose the known impurities and degradants identified above. Each such failure also constitutes a violation of the false claims act and similar state statutes.

**J. GILEAD INVESTIGATIONAL DRUG "GS 9190," WHICH HAS A HISTORY OF UNREPORTED, SIGNIFICANT MANUFACTURING PROBLEMS, CAUSES "SERIOUS ADVERSE EVENTS" IN TWO CLINICAL TRIALS.**

329. In a press release issued on September 4, 2011 [REDACTED] Gilead announced that it was amending the design of two ongoing clinical trials to discontinue the dosing of clinical trial drug "GS 9190" (an investigational drug to treat Hepatitis C) to patients who had been receiving the compound in combination with several other drugs across the two studies.

330. As Gilead explained in the press release, "[t]his decision follows reports of two serious adverse events in patients enrolled in two separate studies who were receiving GS 9190."

331. The press release did not specify the nature of the adverse events or their cause, and the Relators are not privy to this information. The use of the word "serious" implies that study participants, whose inclusion criteria requires a chronic Hepatitis C infection, died during the respective studies, and that Gilead believed that GS 9190 caused or contributed to their death.

332. Given Gilead's notification to the FDA and voluntary discontinuance of the use of GS 9190 in an arm of each of the studies, the FDA would not ordinarily investigate the root cause(s) of the test patients' serious adverse events or require Gilead to do so. The

1 assumption is that adverse events in such studies are caused by problems with the drug's  
2 formulation or interaction with other study medication. There would ordinarily be no  
3 reason to suspect that poor manufacturing practices contributed to or caused the events.  
4 As described below, however, there is reason to suspect that here.

5  
6 333. GS 9190 is an oral suspension/solution product that is manufactured as a two-piece  
7 capsule. It is produced for Gilead by several CMOs. Clinical supplies have been  
8 manufactured both by Aptuit and by Patheon (the latter from its Cincinnati, Ohio  
9 facility), with leakage noted in capsules from both manufacturers. Since 2006, Relator  
10 Sherilyn Campie's group has been involved in stability testing of the GS 9190 clinical  
11 material.  
12

13  
14 334. The leakage associated with GS 9190 capsules has been common lore within the  
15 company and at its contract manufacturers since 2008, and has been historically  
16 attributed to the liquid escaping between the overlapping capsule pieces.

17  
18 335. This is a design flaw that inevitably worsens over time and is aggravated by temperature  
19 excursions and jostling or movement of the capsules during shipping and storage. The  
20 investigation associated with the most recent events, QI10-015, from 2010, remains  
21 "open" after years. [REDACTED]  
22

23 336. Rather than dedicate resources to developing a two-piece capsule which maintains its  
24 integrity, the company's quality assurance function approved sampling instructions for  
25 the stability testing of the GS 9190 capsule that are designed to mask the leaking, sub-  
26  
27  
28

1 potent capsules by selecting only capsules weighing within a predefined weight range for  
2 testing.

3 337. Responsible for coordinating the stability testing of clinical drugs for quality control, Ms.  
4 Campie has maintained several project-related files on the GS 9190 compound. One such  
5 folder is entitled "leaking capsules," [REDACTED] The  
6 most recent entry to the folder is from April 2011, months before the press release  
7 announcing the compound's discontinuance in the two clinical trials.  
8

9 338. As reflected in Ms. Campie's "leaking capsules" file [REDACTED] and providing  
10 evidence of the chronic nature of the issue, GS 9190 capsules removed from their bottles  
11 to support stability testing in April 2011 "were slippery to the touch" due to leakage. At  
12 the time of noting this observation, the lot AL1007A1 was approximately 3 months old.  
13 The product has a two-year expiration date.  
14

15 339. Ms. Campie and her team were required to follow an approved quality assurance stability  
16 protocol when evaluating the capsules inside the remaining bottles of the lot for leakage,  
17 prior to using them to generate stability data, by determining whether the capsules had  
18 maintained their weight during storage. [REDACTED]  
19

20 340. Ms. Campie reported the results to quality assurance, noting that two such values were  
21 failing the arbitrarily-assigned weight range. Gilead was apparently determined to keep  
22 the capsules in the clinic - notwithstanding these results - as no subsequent clinical hold  
23 or recall activities ensued.  
24  
25  
26  
27  
28

1 341. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 342. [REDACTED]

11 [REDACTED] (based on the calculation used,

12 several capsules would still have been above 100% potent.)

13 343. Similar leaking was observed in capsules from the same lot that had been stored at two

14 alternative temperatures; with capsules from the 40C/75RH storage condition Exhibiting

15 a potency range from approximately [REDACTED] to [REDACTED] potent. [REDACTED]

16 344. Another lot of capsules – lot AL1001A2 – was also found to have leaking capsules.

17 [REDACTED] Gilead again utilized the established testing criteria, specifically

18 designed to obscure the variation in capsule strength and allow for the continued use of

19 the capsules in clinical studies.

20 345. [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED] Only capsules that made weight would be

26 [REDACTED]

27 [REDACTED]

28 [REDACTED]

1 subjected to further testing, cherry-picking the top performers to stack the decks for  
2 passing the tests.

3 346. Moreover, Gilead instructed its analysts to ignore the fact that "the imprints on some of  
4 the capsules may be faded or not present" due to the leaking. [REDACTED]  
5

6 347. Despite these clear appearance flaws the testers were required to report "conforms" when  
7 performing appearance testing for those capsules. Analysts were only to note appearance  
8 issues "for informational purposes" – the "conforms" label would follow the "leaking"  
9 capsules to be used in the clinical trial as if there were no immediate or known latent  
10 issues with the capsules. [REDACTED]  
11

12 348. As reflected in the remaining pages of Ms. Campie's leaking capsules file, testing of GS  
13 9190 lots showed varying degrees of weight loss at virtually all environmental conditions  
14

15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 349. [REDACTED]  
20 [REDACTED] The [REDACTED] potency  
21 value is well under the lower limit for capsule potency at time of release (at NLT 95%) as  
22 filed in the Gilead GS 9190 IND application with the FDA.  
23

24 350. This is particularly notable because this testing was completed just three months after  
25 their manufacture date, indicating that the weight loss from unabated leakage would  
26  
27  
28

1 continue and quickly exceed any "limit" assigned to the metric by Gilead, even for those  
2 capsules that for the time being appeared to have maintained sufficient weight.

3 351. Gilead did not even bother to set an allowable range of weight for the empty capsules  
4 prior to releasing them for filling while the average weight of the filled capsules is  
5 calculated based on the weight of twenty (20) capsules from a batch size of 50,000, a  
6 glaring and unacceptable omission of quality control. [REDACTED]  
7

8 352. Using the company's own self-derived formula [REDACTED]  
9 [REDACTED] the observed potency value of 86% observed in lot AL1007A1 of GS 9190 capsules  
10 should have resulted in communication with the FDA and removal of the lot (or lots)  
11 from the clinical studies.  
12

13 353. Moreover, given the highly selective nature of capsule selection in the company, the  
14 incidence rate of sub-potent, underweight capsules provided to the clinic from the  
15 referenced lot should be much higher.  
16

17 354. These issues were not new to Gilead with respect to GS 9190. Gilead had been aware of  
18 leaking problems with the product for years.  
19

20 355. In February 2011, a director in Gilead's Analytical Chemistry group, [REDACTED]  
21 [REDACTED] stating that Gilead wanted to ship  
22 GS 9190 capsules to its bottler "ASAP ... to avoid the potential for leakers contaminating  
23 the batch," even though both quality assurance and quality control knew that, due to the  
24 leakage issues, the product did not conform to specification. [REDACTED]  
25  
26  
27  
28

1 356. Nor were Gilead's efforts to test around the issue isolated. [REDACTED]

2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]

13  
14 357. Making matters worse, the analytical results of the so-called non-"critical" attributes were  
15 available, but the impurity profile was shielded from review in a separate database that  
16 was not provided to quality assurance. [REDACTED]

17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]

21  
22 358. [REDACTED]

23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28

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1 359. There is no "suitable solution" to testing and quality control of investigational drug  
2 products other than to test them against the appropriate specification in all respects, and  
3 to publish the results. As is often the case at Gilead, however, this was not the sort of  
4 solution that Gilead was looking for.  
5

6 360. Gilead has been manipulating the specifications and testing for GS 9190 since at least  
7 2008.  
8

9 361. In emails from August 2009 [REDACTED] managers in quality control and quality  
10 assurance discuss testing of an early lot of GS 9190. It is clear from the discussion that  
11 the testing of the lot was selective rather than thorough, and that data was available but  
12 not considered. [REDACTED]  
13 [REDACTED]  
14 [REDACTED]

15  
16 362. [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25  
26  
27  
28

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1 363. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4

5 364. It appears that Gilead went ahead and used the wrong specifications for their stability

6 testing anyway. Shortly after the email exchange, both the German and Irish regulatory

7 authorities made note of Gilead's failure to submit appropriate stability data and required

8 justification and further testing. (See Sept. 30, 2009 letter from German BfArM

9 [REDACTED] ("only lots with different

10 composition are cited as evidence of shelf life .... It has to be demonstrated that also the

11 new formulation without antioxidants is stable enough."); Oct. 5, 2009 letter from Irish

12 Medicines Board, [REDACTED] ("it is noted that the stability

13 results provided for GS 9190 capsules were generated using a formulation which

14 contained the antioxidants BHT and BHA. These have since been removed from the

15 formulation and no stability results have been provided for the new antioxidant-free

16 formulation .... [j]ustification for this procedure should be provided.") the Relators do

17 not believe that the FDA similarly caught Gilead's flawed stability testing or required

18 additional justification.

19

20

21

22

23 365. Gilead's IND for GS 9190 contained false statements and material omissions, in that it

24 listed ingredients that did not include the contaminations discovered no later than 2008.

25 These false statements and material omissions were intentional, as Gilead knew about the

26 impurities at the time of the IND filing.

27

28

1 366. Gilead never submitted a supplemental IND in order to obtain FDA approval for the  
2 inclusion of the contaminants in its final drug products.

3 367. If the FDA had known about the false statements and material omissions, or if had known  
4 that the drugs had these impurities, it would not have allowed the clinical trials to proceed  
5 or would have placed a clinical trial hold on the studies once it learned of them.  
6

7 368. Gilead knew this to be true, which is why it decided not to disclose the impurities and  
8 contaminations to the government in its IND filing or in any subsequent disclosures.  
9

10 369. All claims presented to the federal and state governments for these drugs constitute false  
11 claims for unapproved or fraudulently-approved drug products in violation of the false  
12 claims act and similar state statutes.  
13

14 370. All batches of GS 9190 manufactured with these contaminants were unapproved for use  
15 in clinical trials.  
16

17 371. The presence of these unapproved contaminants renders these drugs "adulterated," as  
18 defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the  
19 sale of the adulterated and misbranded drugs constitutes a violation of the false claims act  
20 and similar state statutes.  
21

22 372. In addition, the federal government sponsored, funded, and/or approved the drug trials  
23 involving these undisclosed, tainted products. Gilead was required to identify and  
24 disclose any new or known impurity or degradants in the API supplied to these studies  
25 (under 21 C.F.R. 56.108(b)). Yet Gilead failed to disclose the known impurities and  
26  
27  
28

degradants identified above. Each such failure also constitutes a violation of the False Claims Act and similar state statutes.

**K. COMPARATOR DRUG "PEGASYS," PREVIOUSLY DEEMED "UNUSABLE" AFTER BEING SUBJECTED TO TEMPERATURE ABUSE, IS NEVERTHELESS DOSED TO PATIENTS IN CLINICAL TRIALS, INCLUDING IN A GS 9190 TRIAL.**

373. To assess the safety and efficacy of several investigational drugs in the treatment of chronic Hepatitis C infections, Gilead initiated multiple clinical trials that incorporated comparator drugs (i.e., drugs that the investigational drug is being compared to).
374. One such trial, GS-US-196-0140, included 144 study locations spanning 29 states and 7 foreign countries, with an estimated total enrollment of 320 participants. (see summary of study, attached as [REDACTED])
375. Another trial was one of the two GS 9190 trials described above that experienced a serious adverse event. The comparator drugs selected, both widely prescribed for the treatment of chronic Hepatitis C, were the biologic Pegasys (Peg Interferon alfa-2a, by Roche) and Copegus (Ribavirin, also by Roche).
376. All study drugs, including the comparators, were provided to the clinics from Gilead's San Dimas facility, with the Pegasys comparator supplied as a "pre-filled" syringe for injection and the Copegus as an oral solid tablet dose.
377. As with all drugs used in a clinical study, it was imperative that the comparator drugs be maintained under the strict controls set forth in their federally-approved labeling.
378. For Pegasys, that labeling could not be more clear: "store PEGASYS prefilled syringes in a refrigerator, at 36F to 46F (2C to 8C). Do not leave PEGASYS out of the refrigerator

1 for more than 24 hours. Do not freeze or shake PEGASYS." [REDACTED] (emphasis  
2 added).)

3 379. In an apparent effort to minimize packaging-related and transportation costs, Gilead's  
4 method of assuring that the comparator drug would arrive at each clinic at a temperature  
5 consistent with the label was limited to using an unknown number of ice packs and  
6 shipping the drug via fed ex overnight (or priority) delivery service.

7  
8 380. Likewise, instead of providing any quantitative way of assessing the continued suitability  
9 and safety of the drug upon arrival at the clinic, such as temperature indicators on the  
10 packaging, individuals at the clinics were expected to use their own subjective  
11 assessment of the "coolness" of the package upon arrival to gauge compliance with the 2-  
12 8C label.  
13  
14

15 381. Emails between Gilead employees show their own frustration at Gilead's approach. [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]

20 382. [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]

25 383. [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28

1 [REDACTED] The email string ends before anyone provides the cost comparison. Yet there  
2 can be no doubt that the cost of a temperature indicator would be minimal. [REDACTED]  
3 containing a quote of just over \$2 per label for such a product.)

4  
5 384. Nevertheless, it appears that Gilead still has not cured the flawed shipping methods,  
6 preferring to avoid the minimal cost of temperature indicators at the expense of proper  
7 GMP.

8  
9 385. These practices resulted in patients being dosed with drug products that had experienced  
10 temperature excursions well beyond the label limits. On November 2, 2011, Relator  
11 Sherilyn Campie was copied on an email thread from August relating to Pegasys clinical  
12 trial drug which was sent by Gilead to numerous study sites on June 16, 2011, via Fed Ex  
13 for delivery the following day. [REDACTED]  
14

15 386. Apparently due to flooding in the Memphis area, the shipments were held at the Memphis  
16 Fed Ex warehouse until delivery on June 20, 2011. On June 24, 2011, Gilead obtained  
17 information regarding the temperature in the Memphis warehouse from June 16-18,  
18 2011. The data showed that the maximum daily temperatures that the drug was exposed  
19 to approached 95, 89 and 92F (or 32 to 35C), respectively, on the days in question. [REDACTED]  
20  
21 [REDACTED]  
22

23 387. Despite this documented temperature excursion, there was no immediate request by  
24 Gilead to return the material, and quality assurance did not even assess the shipping  
25 delay's impact on the study drug until August 25, 2011, due to [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28

1 388. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4

5 389. Unfortunately, it appears that at least one site of the eleven that received the product

6 nevertheless administered the drug. [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 390. Knowing that the clinical drug had been subjected to temperatures well outside of the

13 label, accented by the saes which had occurred in the study (summarized above), and

14 with an understanding of the impact of elevated temperatures on biologics – namely, to

15 render the drug ineffective or dangerous – the Gilead manager's suggestion for a path

16 forward was as follows: [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 391. This statement perfectly captures both Gilead's lack of proper GMP controls and

24 procedures and its corporate culture emphasizing product use no matter the circumstance.

25 392. The federal government sponsored and/or funded the drug trials involving these

26 undisclosed, tainted products. Gilead was required to identify and disclose any new or

27

28

1 known impurity or degradants in the API supplied to these studies. Yet Gilead failed to  
2 disclose the known impurities and degradants identified above. Each such failure also  
3 constitutes a violation of the false claims act and similar state statutes.

4  
5 **L. "RANOLAZINE IV" FAILS APPEARANCE TESTING DUE TO THE**  
6 **PRESENCE OF VISIBLE FOREIGN MATTER IN "STERILE"**  
7 **SOLUTION, BUT IS STILL PROVIDED TO PATIENTS IN A CLINICAL**  
8 **TRIAL.**

9 393. In April 2010, in an attempt to broaden the existing indications for "Ranexa," approved in  
10 an oral, solid-dose form for the treatment of chronic angina, Gilead initiated a clinical  
11 study (GS-US-270-0101/NCT01163734) using an investigational intravenous  
12 formulation called "Ranolazine IV." (see summary of clinical trial, [REDACTED])

13 [REDACTED] The new drug, a sterile liquid-dose formulation, is composed of the same API  
14 (Ranolazine) found in the tablet formulation.

15 394. To minimize additional investment and potential delays associated with manufacturing  
16 new clinical trial batches, the company decided to utilize vials from a Ranolazine IV  
17 batch (lot 903715) that had been manufactured for CV Therapeutics in September 2006.

18 395. Vials from the batch had been placed on stability at PPD, a contract testing organization,  
19 in December 2006 for the purpose of establishing a four-year expiration date for the  
20 intravenous formulation.

21 396. Three years later, in December 2009, and with only two years' worth of stability data at  
22 the time, Gilead decided to use the batch of clinical drug in the trial, [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

1 397. [REDACTED]

2 [REDACTED] On

3 December 16, 2010, the 48-month testing of inverted vials from the Ranolazine lot began.

4 398. [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 399. [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 400. After receiving the communication regarding the *appearance* test failures – a minimal  
 15 testing criteria where failure should raise immediate red flags – and with the knowledge  
 16 that they had an ongoing clinical trial in progress in which patients were receiving the  
 17 tainted drug *intravenously*, Gilead should have immediately: (i) issued a hold on the  
 18 study; (ii) notified those involved in the study's oversight; (iii) communicated that a  
 19 "product problem" event had occurred via the FDA's Medwatch reporting system; and  
 20 (iv) reassessed the root cause of any serious adverse events (SAEs) which had occurred in  
 21 the study.  
 22  
 23  
 24

25 <sup>7</sup> The extended date was not and could not have been supported by existing data given that the stability lots were just three  
 26 years old at the time. Moreover, the Ranolazine intravenous dosage form had never been subjected to an extractable and  
 27 leachable study to assess the compatibility between the container/closure and study drug. As such, it would not have been  
 28 possible for Gilead to assess the safety and efficacy of the drug prior to dosing study participants.

1 401. Such actions would have been a consistent application of long-standing regulatory  
2 expectations associated with product deemed *adulterated* under section 501(a)(2)(b) of  
3 the FDCA. (See also FDA Medwatch reporting guidelines, [REDACTED]  
4 [REDACTED]  
5 [REDACTED]

6 402. [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]

10 403. On December 27, 2010, in a telling example of their indifference to the safety of the test  
11 patients, Gilead closed its Foster City campus for a planned week-long shutdown, yet  
12 Gilead took none of the steps outlined above prior to or during closure while the test  
13 patients continued to be subjected to the drug.  
14

15 404. In contrast to the disinterest exhibited by Gilead, numerous contemporaneous examples  
16 of recalls undertaken by other pharmaceutical companies in response to failing  
17 "appearance" test criteria abound, including in connection with observations of visible  
18 "particulate matter" similar to that used to describe the appearance of Gilead's clinical  
19 trial drug:  
20  
21

22 A. On October 29, 2010, sandoz and the fda notified healthcare professionals of a  
23 recall of methotrexate injection due to "small glass flakes detected in a limited  
24 number of vials in four lots." [REDACTED]  
25

26 B. On May 5, 2011, Luitpold Pharmaceuticals initiated a recall of Caffeine &  
27 Sodium Benzoate injection lot 0084 due to the presence of particulate matter on  
28

the basis that "visual particulate matter was observed in some retained vials and stability samples." [REDACTED]

C. From February to July 2011, American Regent initiated a recall of injectable products "because some vials Exhibit translucent visible particles consistent with glass delamination." [REDACTED]

405. On January 07, 2011, PPD sent Gilead summary documents, titled "*un-audited draft*" COAs, which contained the dates of analysis, product specifications, and results associated with the testing performed at the 48-month interval for both upright and inverted vials of ranolazine IV.

406. For the "appearance" criteria, the COA states "*clear, no visible particles*" and a "passing" result for the upright vials. For the inverted vials, the COA's substitute the failing results described above with a [REDACTED] apparently a placeholder while PPD awaited instructions from Gilead. [REDACTED]

407. Also on January 07, 2011, PPD sent an email to Gilead which contained a running narrative of the microscopy results of the vials, accompanied by photographs. [REDACTED]

\* For a marketed (approved) drug, typically the manufacturer would voluntarily file an FDA NDA Field Alert within 72 hours after discovery of adulterated drug product, followed by a Class I or Class II recall. If the event is not addressed adequately and is subsequently found during the course of an inspection, the issuance of a Warning Letter may occur. (See Exh. Q(9), FDA Warning Letter to Luitpold Pharmaceuticals arising from the same issue.)

1 408. On January 10, 2011, Relator Sherilyn Campie was invited to a meeting at Gilead,  
2 described in the calendar entry as a meeting [REDACTED]

3 [REDACTED]  
4 [REDACTED]  
5 409. [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]

10 410. A "pre-MRB" meeting indicates that the company was having difficulty deciding whether  
11 to keep non-conforming product in the clinic -- they were not yet ready to convene an  
12 actual MRB meeting (which Sherilyn would not have been part of), instead delaying the  
13 process through pre-meetings such as this one.  
14

15 411. Senior management present at the meeting included Senior Vice President Taiyin Yang  
16 and Senior Director Tammis Matzinger. PPD's findings of visible adulterants was  
17 discussed.  
18

19 412. Later in the week, January 13, 2011, a Gilead study management team meeting was held  
20 for the GS-US-270-0101 study. As she was not a member of the study team, Sherilyn was  
21 not invited to the meeting. But she was provided with a copy of the agenda. [REDACTED]  
22 [REDACTED]  
23 [REDACTED]

24 413. [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28

1 [REDACTED]  
2 [REDACTED]  
3 414. [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8  
9 415. This is a significant number of SAEs for a patient study population of just twelve,  
10 equating to a 25% occurrence rate. It suggests that a causality may exist between the  
11 adverse events and the use of the tainted trial drug.  
12  
13 416. As evidenced in the recall examples listed above at [REDACTED]  
14 [REDACTED] contaminations such as those here ordinarily results in recalls due to the *mere*  
15 *possibility* of adverse events.  
16  
17 417. The following day, PPD provided Gilead with a preliminary investigation report [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20  
21 418. So at the same time that Gilead and the study team were discussing testing on patients  
22 through the end of January 2011, Gilead was being updated on a significant  
23 contamination/adulteration issue in the same clinical material, the same issue that had  
24 been known since mid-December 2010. Yet the latter seemed to have no effect on the  
25 former. Testing of human subjects continued.  
26  
27  
28

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1 419. On February 16, 2011, Gilead received the results from vials sent to McCrone Institute of  
2 Westmont, Illinois for the purpose of identifying observed particulates in the vials. The  
3 results from ten vials indicated the [REDACTED]  
4 [REDACTED] which cannot  
5 be detected via the current test methods. [REDACTED]  
6

7 420. Additional communication regarding the stability appearance issue was documented in a  
8 report provided to Gilead by PPD dated February 22, 2011. [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13

14 421. The report also contains references to additional testing of several hundred vials and  
15 additional observations of appearance failures due to the presence of foreign matter on  
16 January 06, 2011, January 12, 2011, January 13, 2011, January 28, 2011, February 05,  
17 2011 and February 08, 2011.  
18

19 422. Shortly thereafter, a *draft* Gilead report was generated [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

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1 423. [REDACTED]

2 [REDACTED] Such a reduction would of course  
3 have no retroactive effect on the particulate contamination that had been observed in drug  
4 product that was already provided to test patients. Moreover, the decision implies that  
5 the trial drug was never suitable beyond three years, should never have been tested on  
6 patients, and that the results of the study are or should be negated or deemed invalid.  
7

8 424. From the initial email communication of the *appearance* failures on December 20, 2010,  
9 to the photographs of the vials in question, to the clinical study team meeting agenda, to  
10 the reports, it is evident that Gilead had no intention of informing the FDA of any issues  
11 with the trial drug.  
12

13 425. Moreover, the content of Gilead's final, approved investigation report (QI11-001), signed  
14 on April 01, 2011, *is not consistent with significant events associated with the clinical*  
15 *trial and omits all meaningful data related to potential patient safety issues.* [REDACTED]  
16 [REDACTED]  
17 [REDACTED]

18  
19 426. [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25

26 427. All of these statements are inconsistent with the previous reports, tests, and observations,  
27 and are false and misleading.  
28

1 428. In reality, Gilead knew of visible foreign material for over a month while they continued  
2 to use the drug on clinical patients in a study in which there had already been serious  
3 adverse events.

4 429. Gilead's final investigation report for Ranolazine IV contained false statements and  
5 material omissions, in that it omitted meaningful data related to potential patient safety  
6 issues and falsified information about significant events associated with the trial. These  
7 false statements and material omissions were intentional, as Gilead knew about the  
8 impurities at the time of the investigation report.

9 430. Gilead never submitted a supplemental report in order to obtain FDA approval for  
10 continuing with the study.

11 431. If the FDA had known that the drugs had these impurities, it would have requested a  
12 recall of the study drugs.

13 432. Gilead knew this to be true, which is why it decided not to disclose these issues to the  
14 government in its final investigation report or in any subsequent disclosures.

15 433. All claims presented to the federal and state governments for these drugs constitute false  
16 claims for unapproved or fraudulently-approved drug productions in violation of the false  
17 claims act and similar state statutes.

18 434. The presence of these unapproved contaminants renders these drugs "adulterated," as  
19 defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the  
20 sale of the adulterated and misbranded drugs constitutes a violation of the false claims act  
21 and similar state statutes.

1 435. In addition, the federal government sponsored and/or funded the drug trials involving  
2 these undisclosed, tainted products. Gilead was required to identify and disclose any new  
3 or known impurity or degradants in the API supplied to these studies. Yet Gilead failed  
4 to disclose the known impurities and degradants identified above. Each such failure also  
5 constitutes a violation of the false claims act and similar state statutes.  
6

7 **M. GILEAD'S STRIBILD PILL FOR HIV, AND ONE OF STRIBILD'S**  
8 **COMPONENT DRUGS "COBICISTAT," HAVE EXPERIENCED**  
9 **QUALITY AND INTEGRITY ISSUES THAT HAVE NOT BEEN**  
10 **DISCLOSED TO THE GOVERNMENT.**

11 436. Gilead's successor to its blockbuster HIV drug Atripla is the new four-drug pill Stribild,  
12 previously referred to as "Quad", summarized in Gilead's press releases, Stribild contains  
13 four Gilead compounds in a once-daily tablet: Elvitegravir, an investigational integrase  
14 inhibitor; Cobicistat, a "boosting" agent designed to boost blood levels of HIV medicines;  
15 and Truvada (itself a combination drug of APIs FTC and TDF).  
16

17 437. In August 2011, Gilead announced that the new drug cleared an important hurdle as  
18 researchers reported that Stribild "proved non-inferior to the marketed drug in a new  
19 study."  
20

21 438. Gilead finished late-stage testing in 2011. It submitted the marketing application for  
22 Stribild to the FDA on October 27, 2011. Cobicistat ("COBI"), one of the component  
23 drugs in Stribild, is also being evaluated as a stand-alone boosting agent for other  
24 antiretrovirals.  
25

26 439. In July 2011, Gilead announced that it had reached an agreement with the medicines  
27 patent pool foundation to license Stribild (then referred to as Quad), COBI and other  
28

1 investigational drugs to create affordable access to HIV/AIDS and other populations in  
2 the developing world. [REDACTED]  
3 [REDACTED]  
4 [REDACTED]

5 440. These announcements, intended by Gilead to cause excitement in (and eventually billions  
6 in revenue from) the HIV/AIDS community and those that serve it, raise red flags.

7 441. Yet testing performed by or on behalf of Gilead on the Quad and COBI revealed quality  
8 and integrity issues. Moreover, Gilead appears to be attempting to shield those issues  
9 from the government regulators and inspectors. The following describes what the  
10 Relators have learned thus far.

11  
12 442. As recently as June 2011, Gilead's Quality Assurance group was made aware of red  
13 foreign material of unknown origin in Quad tablets. [REDACTED]  
14 [REDACTED]

15 Littler, a senior specialist in Gilead's quality assurance group.) The foreign material is  
16 identified as polyethylene. While the analyst that authored the report surmises that the  
17 material may have come from red twist ties used to secure drug product excipients and  
18 API, certain properties of the material are inconsistent with that hypothesis. [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]

22 443. It appears that the incident was not isolated to a single occurrence – chemistry analyses in  
23 the report suggest testing done on what must have been different tablets weeks apart.  
24 [REDACTED]  
25 [REDACTED]

26 444. Indeed, Gilead began seeing contamination issues in both Quad and COBI from the very  
27 first lots that were manufactured using a new source of Silicon dioxide in early 2011.  
28

1 Silicon dioxide ("SiO<sub>2</sub>") is used as a carrier or absorbent for COBI API. The original  
2 SiO<sub>2</sub> used by Gilead for these drugs was a [REDACTED] SiO<sub>2</sub> called [REDACTED] which is  
3 [REDACTED]. In early 2011, apparently in an effort to decrease costs, Gilead  
4 commissioned a second, [REDACTED] source of SiO<sub>2</sub>, [REDACTED]  
5 [REDACTED]  
6 [REDACTED]

7 445. On February 28, 2011, Relator Sherilyn Campie was provided with two stability  
8 assessments for Quad and COBI by Mr. Littler of quality assurance. [REDACTED]  
9 [REDACTED]

10 446. Mr. Littler explained to Ms. Campie that "[t]hese are the first lots using COBI API on  
11 [REDACTED]  
12 [REDACTED]

13 447. Within just a few weeks, Ms. Campie was made aware of "foreign material on the Quad  
14 lot using [REDACTED] Again, the issue was "red material embedded in  
15 our Quad stability lot." And again, due to the different timing of the discovery and  
16 testing, this had to be a different instance of red material than the June 2011 event  
17 described above [REDACTED]  
18 [REDACTED]

19 448. Patheon, the CMO, denied that the red material was from the "red twist ties Patheon used  
20 in the manufacturing area," saying that it suspected instead that the foreign matter "came  
21 in with the material" [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]

25 449. That the [REDACTED] SiO<sub>2</sub> might be inadequate or contaminated with foreign material would  
26 have come as no surprise to Gilead. [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

1 [REDACTED]  
 2 [REDACTED]  
 3 [REDACTED]  
 4 [REDACTED]  
 5 [REDACTED]  
 6 450. By then, Gilead was already working on adjusting its testing protocols so that [REDACTED]  
 7 product would show passing grades. Testing for homogeneity would use samples only  
 8 from the middle and top part of each drum, but not the bottom, representing an  
 9 acknowledged but unexplained "change [in] controls." [REDACTED]  
 10 [REDACTED]  
 11 [REDACTED]  
 12 [REDACTED]  
 13 [REDACTED]

14 451. If there was no testing for heavy metals, Gilead apparently reasoned, they wouldn't be  
 15 discovered, and they would not have to be reported. [REDACTED]  
 16 [REDACTED]  
 17 [REDACTED]  
 18 [REDACTED]  
 19 [REDACTED]  
 20 [REDACTED]

21 [REDACTED] Compare with  
 22 Gilead's quality specification for COBI [REDACTED] a document that is provided to the  
 23 government, where none of these metals is listed.)

24 452. Ms. Campie noticed something else that was strange regarding the new [REDACTED] SiO<sub>2</sub>.  
 25 Both the [REDACTED] SiO<sub>2</sub> [REDACTED] and the [REDACTED] SiO<sub>2</sub> [REDACTED] have the same Gilead  
 26 part number (PC-11139), even though the substances are clearly different, one being  
 27 [REDACTED]  
 28 [REDACTED]

1 [REDACTED] and the other not, and with substantially distinct testing histories. [REDACTED]

2 Both are sent to Patheon for use in manufacturing the Quad (now Stribild) and COBI.

3 453. Given that they are sent to and stored by Patheon under the same part number, it would  
4 be difficult if not impossible to segregate or differentiate the source of the SiO<sub>2</sub> [REDACTED]  
5 versus [REDACTED] in the event that an investigation was initiated. This alone shows an  
6 unacceptable lack of cGMP and control. Ms. Campie immediately challenged Mr. Littler  
7 to explain this upon receiving his February 28 email, but she never received a response.  
8

9  
10 454. The use of the same part number for both SiO<sub>2</sub> sources shows more than a lack of  
11 control. It again demonstrates Gilead's affirmative efforts to hide its actual, highly-  
12 flawed manufacturing processes from the government.  
13

14 455. Indeed, it appears that Gilead has never disclosed to the government that it has secured a  
15 second source of SiO<sub>2</sub>, or that it has experienced significant manufacturing issues since.  
16 The government is only aware of [REDACTED] SiO<sub>2</sub> manufactured by [REDACTED].  
17

18 456. But since Gilead uses the same part number for [REDACTED] SiO<sub>2</sub>, it would be difficult for a  
19 government regulator or inspector to discern the new API source, let alone to determine  
20 that there are observed manufacturing flaws that are ongoing at that source.  
21

22 457. Similarly, Gilead recently "updated" its quality specification for COBI by removing the  
23 term [REDACTED] from the COBI API description, thereby removing any reference to an  
24 [REDACTED]-specific product. [REDACTED] Gilead would expect the government to miss  
25 this subtle change to the specification, and yet would undoubtedly point to it as adequate  
26 disclosure if the new source were ever discovered.  
27  
28

1 458. Gilead's NDA for Stribild contained false statements and material omissions, in that it  
2 listed ingredients that did not include the contaminations discovered no later than June  
3 2011. These false statements and material omissions were intentional, as Gilead knew  
4 about the impurities at the time of the NDA.  
5

6 459. Gilead never submitted a supplemental NDA in order to obtain FDA approval for the  
7 inclusion of the contaminants in its final drug products.  
8

9 460. Stribild was approved by the FDA on August 27, 2012. If the FDA had known about the  
10 false statements and material omissions, or if had known that the drugs had these  
11 impurities, it would not have granted approval of the new formulation, or would have  
12 withdrawn approval once it learned of them. 21 U.S.C. § 355(e)(5).  
13

14 461. Gilead knew this to be true, which is why it decided not to disclose the impurities and  
15 contaminations to the government in its NDA or in any subsequent disclosures.  
16

17 462. All claims presented to the federal and state governments for these drugs constitute false  
18 claims for unapproved or fraudulently-approved drug productions in violation of the false  
19 claims act and similar state statutes.  
20

21 463. All batches of Stribild manufactured with these contaminants were unapproved for sale in  
22 interstate commerce.

23 464. The presence of these unapproved contaminants renders these drugs "adulterated," as  
24 defined by 21 U.S.C. § 351, and "misbranded," as defined by 21 U.S.C. § 352, and the  
25 sale of the adulterated and misbranded drugs constitutes a violation of the false claims act  
26 and similar state statutes.  
27  
28

1 465. In addition, the federal government sponsored and/or funded the drug trials involving  
2 these undisclosed, tainted products. Gilead was required to identify and disclose any new  
3 or known impurity or degradants in the API supplied to these studies. Yet Gilead failed  
4 to disclose the known impurities and degradants identified above. Each such failure also  
5 constitutes a violation of the false claims act and similar state statutes.  
6

7 **CONCLUSION**

8 466. During the times relevant to this complaint, defendants released to the market and made  
9 and/or caused to be made claims to government health programs for drugs that were  
10 manufactured in unregistered facilities and/or were defective, misidentified, not  
11 manufactured in accordance with FDA approved processes, and/or did not come with the  
12 assurance of identity, strength, quality and purity required for distribution to patients;  
13 and/or the approvals for which were obtained through false representations to the FDA.  
14

15 467. These false claims arose out of chronic, serious deficiencies in defendants' quality  
16 assurance functions and defendants' ongoing serious violations of the laws and  
17 regulations designed to ensure the fitness of drug products for use, include the federal  
18 Food, Drug and Cosmetics act, 21 U.S.C. §§ 301, et seq., and the Code of Federal  
19 Regulations, title 21. Gilead lied to the FDA in order to conceal its inability and/or  
20 unwillingness to correct these quality failures and legal and regulatory violations.  
21  
22  
23  
24  
25  
26  
27  
28

**CAUSES OF ACTION**

**COUNT ONE**

**31 U.S.C. §3729(A)(1)(A)**

**(PRESENTING AND/OR CAUSING OTHERS TO PRESENT CLAIMS FOR UNAPPROVED, ADULTERATED, AND/OR ILLEGALLY IMPORTED API)**

468. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

469. This is a claim for penalties and treble damages under the federal False Claims Act.

470. By virtue of the acts described above, defendants, for the purpose of defrauding the government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under the Medicare, Medicaid and other government health programs to officers, employees or agents of the United States government, within the meaning of 31 U.S.C. § 3729(a)(1)(a).

471. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the government.

472. Therefore, the federal government has been damaged in an amount to be proven at trial. Damages to the federal government include, but are not limited to, three times the full value of any such fraudulent claims.

473. Additionally, the federal government is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by defendants and arising from their fraudulent conduct as described herein.

**COUNT TWO**

**31 U.S.C. §3729(a)(1)(B)**

**(Making and/or Causing Others to Make Material False Statements)**

474. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

475. This is a claim for penalties and treble damages under the federal false claims act.

476. By virtue of the acts described above, defendants, for the purpose of defrauding the government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under the Medicare, Medicaid and other government health programs to officers, employees or agents of the United States government, within the meaning of 31 U.S.C. § 3729(a)(1)(b).

477. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the government.

478. Therefore, the federal government has been damaged in an amount to be proven at trial. Damages to the federal government include, but are not limited to, three times the full value of any such fraudulent claims.

479. Additionally, the federal government is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim paid or approved arising from the defendants' fraudulent conduct as described herein.

**COUNT THREE**

**31 U.S.C. §3729(a)(1)(C)  
(Conspiring to Violate the False Claims Act)**

480. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

481. This is a claim for penalties and treble damages under the federal false claims act.

482. By virtue of the acts described above, defendants knowingly entered into and furthered a conspiracy to defraud the United States by knowingly participating in presenting and/or causing to be presented false or fraudulent records or statements to get false and fraudulent claims paid or approved under the Medicare, Medicaid and other government health programs to officers, employees or agents of the United States government, within the meaning of 31 U.S.C. § 3729(a)(1)(c).

483. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the government.

484. Therefore, the federal government has been damaged in an amount to be proven at trial. Damages to the federal government include, but are not limited to, three times the full value of any such fraudulent claims.

485. Additionally, the federal government is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim paid or approved arising from the defendants' fraudulent conduct as described herein.

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**COUNT FOUR**

**California False Claims Act  
Cal Gov't Code §12651(a)(1), (2) and (3)**

486. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

487. This is a claim for penalties and treble damages under the California false claims act.

488. By virtue of the acts described above, defendants, for the purpose of defrauding the California state government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other California state funded programs to officers, employees or agents of the state within the meaning of Cal. Gov't. Code § 12651(a)(1).

489. By virtue of the acts described above, defendants, for the purpose of defrauding the California state government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other California state funded programs to officers, employees or agents of the state within the meaning of Cal. Gov't. Code § 12651(a)(2).

490. By virtue of the acts described above, defendants knowingly entered into and furthered a conspiracy to defraud the California state government by knowingly participating in presenting and/or causing to be presented false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other California state government programs to officers, employees or agents of the state within the meaning of Cal. Gov't. Code § 12651(a)(3).

1 491. As a result, California state monies were lost through payments made in respect of the  
2 claims and other costs were sustained by the California state government.

3 492. Therefore, the California state government has been damaged in an amount to be proven  
4 at trial. Damages to the state of California include, but are not limited to, three times the  
5 full value of any such fraudulent claims.  
6

7 493. Additionally, the California state government is entitled to the maximum penalty for each  
8 and every false and fraudulent claim made and caused to be made by defendants and  
9 arising from their fraudulent conduct as described herein.  
10

11 **COUNT FIVE**

12 **Delaware False Claims and Reporting Act**  
13 **6 Del C. §1202(a)(1) and (2)**

14 494. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
15 as set forth fully above.  
16

17 495. This is a claim for penalties and treble damages under the Delaware false claims and  
18 reporting act.  
19

20 496. By virtue of the acts described above, defendants, for the purpose of defrauding the  
21 Delaware state government, knowingly presented and/or caused to be presented false or  
22 fraudulent claims for payment or approval under Medicaid and other Delaware state  
23 funded programs to officers, employees or agents of the state within the meaning of 6  
24 Del. C. § 1201(a)(1).  
25

26 497. By virtue of the acts described above, defendants, for the purpose of defrauding the  
27 Delaware state government, knowingly made, used and/or caused to be made or used,  
28

1 false or fraudulent records or statements to get false and fraudulent claims paid or  
2 approved under Medicaid and other Delaware state funded programs to officers,  
3 employees or agents of the state within the meaning of § 6 Del. C. § 1201(a)(1) and (2).

4  
5 498. By virtue of the acts described above, defendants knowingly entered into and furthered a  
6 conspiracy to defraud the Delaware state government by knowingly participating in  
7 presenting and/or causing to be presented false or fraudulent records or statements to get  
8 false and fraudulent claims paid or approved under Medicaid and other Delaware state  
9 government programs to officers, employees or agents of the state within the meaning of  
10 6 Del. C. § 1201(a)(1).  
11

12  
13 499. As a result, Delaware state monies were lost through payments made in respect of the  
14 claims and other costs were sustained by the Delaware state government.

15 500. Therefore, the Delaware state government has been damaged in an amount to be proven  
16 at trial. Damages to the state of Delaware include, but are not limited to, three times the  
17 full value of any such fraudulent claims.  
18

19 501. Additionally, the Delaware state government is entitled to the maximum penalty for each  
20 and every false and fraudulent claim made and caused to be made by defendants and  
21 arising from their fraudulent conduct as described herein.  
22

23 **COUNT SIX**

24 **Florida False Claims Act**  
25 **Fla. Stat. Ann. §68.082(2)**

26 502. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
27 as set forth fully above.  
28

1 503. This is a claim for penalties and treble damages under the Florida False Claims Act.

2 504. By virtue of the acts described above, defendants, for the purpose of defrauding the  
3 Florida state government, knowingly presented and/or caused to be presented false or  
4 fraudulent claims for payment or approval under Medicaid and other Florida state funded  
5 programs to officers, employees or agents of the state within the meaning of Fla. Stat.  
6 Ann. § 68.082(2).  
7

8 505. By virtue of the acts described above, defendants, for the purpose of defrauding the  
9 Florida state government, knowingly made, used and/or caused to be made or used, false  
10 or fraudulent records or statements to get false and fraudulent claims paid or approved  
11 under Medicaid and other Florida state funded programs to officers, employees or agents  
12 of the state within the meaning of Fla. Stat. Ann. § 68.082(2).  
13  
14

15 506. By virtue of the acts described above, defendants knowingly entered into and furthered a  
16 conspiracy to defraud the Florida state government by knowingly participating in  
17 presenting and/or causing to be presented false or fraudulent records or statements to get  
18 false and fraudulent claims paid or approved under Medicaid and other Florida state  
19 government programs to officers, employees or agents of the state within the meaning of  
20 Fla. Stat. Ann. § 68.082(2).  
21  
22

23 507. As a result, Florida state monies were lost through payments made in respect of the  
24 claims and other costs were sustained by the Florida state government.  
25  
26  
27  
28

1 508. Therefore, the Florida state government has been damaged in an amount to be proven at  
2 trial. Damages to the state of Florida include, but are not limited to, three times the full  
3 value of any such fraudulent claims.

4 509. Additionally, the Florida state government is entitled to the maximum penalty for each  
5 and every false and fraudulent claim made and caused to be made by defendants and  
6 arising from their fraudulent conduct as described herein.  
7

8  
9 **COUNT SEVEN**

10 **Georgia False Medicaid Claims Act**  
11 **Ga. Code Ann. §49-4-168 et seq.**

12 510. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
13 as set forth fully above.  
14

15 511. This is a claim for penalties and treble damages under the Georgia False Medicaid Claims  
16 Act.  
17

18 512. By virtue of the acts described above, defendants, for the purpose of defrauding the  
19 Georgia state government, knowingly presented and/or caused to be presented false or  
20 fraudulent claims for payment or approval under the Georgia Medicaid program to  
21 officers, employees or agents of the state within the meaning of Ga. Code Ann. §49-4-  
22 168 et seq.  
23

24 513. By virtue of the acts described above, defendants, for the purpose of defrauding the  
25 Georgia state government, knowingly made, used and/or caused to be made or used, false  
26 or fraudulent records or statements to get false and fraudulent claims paid or approved  
27  
28

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1 under the Georgia Medicaid program to officers, employees or agents of the state within  
2 the meaning of Ga. Code Ann. §49-4-168 et seq.

3 514. By virtue of the acts described above, defendants knowingly entered into and furthered a  
4 conspiracy to defraud the Georgia state government by knowingly participating in  
5 presenting and/or causing to be presented false or fraudulent records or statements to get  
6 false and fraudulent claims paid or approved under the Georgia medicaid program to  
7 officers, employees or agents of the state within the meaning of Ga. Code Ann. §49-4-  
8 168 et seq.  
9

10  
11 515. As a result, Georgia state monies were lost through payments made in respect of the  
12 claims and other costs were sustained by the Georgia state government.  
13

14 516. Therefore, the Georgia state government has been damaged in an amount to be proven at  
15 trial. Damages to the state of Georgia include, but are not limited to, three times the full  
16 value of any such fraudulent claims.  
17

18 517. Additionally, the Georgia state government is entitled to the maximum penalty for each  
19 and every false and fraudulent claim made and caused to be made by defendants and  
20 arising from their fraudulent conduct as described herein.  
21

## 22 **COUNT EIGHT**

### 23 **Hawaii False Claims Act** 24 **Haw. Rev. Stat. §661-21(a)**

25 518. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
26 as set forth fully above.

27 519. This is a claim for penalties and treble damages under the Hawaii False Claims Act.  
28

1 520. By virtue of the acts described above, defendants, for the purpose of defrauding the  
2 Hawaii state government, knowingly presented and/or caused to be presented false or  
3 fraudulent claims for payment or approval under Medicaid and other Hawaii state funded  
4 programs to officers, employees or agents of the state within the meaning of Haw. Rev.  
5 Stat. §661-21(a).  
6

7 521. By virtue of the acts described above, defendants, for the purpose of defrauding the  
8 Hawaii state government, knowingly made, used and/or caused to be made or used, false  
9 or fraudulent records or statements to get false and fraudulent claims paid or approved  
10 under Medicaid and other Hawaii state funded programs to officers, employees or agents  
11 of the state within the meaning of Haw. Rev. Stat. §661-21(a).  
12  
13

14 522. By virtue of the acts described above, defendants knowingly entered into and furthered a  
15 conspiracy to defraud the Hawaii state government by knowingly participating in  
16 presenting and/or causing to be presented false or fraudulent records or statements to get  
17 false and fraudulent claims paid or approved under Medicaid and other Hawaii state  
18 government programs to officers, employees or agents of the state within the meaning of  
19 Haw. Rev. Stat. §661-21(a).  
20  
21

22 523. As a result, Hawaii state monies were lost through payments made in respect of the  
23 claims and other costs were sustained by the Hawaii state government.

24 524. Therefore, the Hawaii state government has been damaged in an amount to be proven at  
25 trial. Damages to the state of Hawaii include, but are not limited to, three times the full  
26 value of any such fraudulent claims.  
27  
28

1 525. Additionally, the Hawaii state government is entitled to the maximum penalty for each  
2 and every false and fraudulent claim made and caused to be made by defendants and  
3 arising from their fraudulent conduct as described herein.  
4

5 **COUNT NINE**

6 **Illinois Whistleblower Reward and Protection Act**  
7 **740 Ill. Comp. Stat. §175/3(a)(1), (2)**

8 526. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
9 as set forth fully above.

10 527. This is a claim for penalties and treble damages under the Illinois Whistleblower Reward  
11 and Protection Act.  
12

13 528. By virtue of the acts described above, defendants, for the purpose of defrauding the  
14 Illinois state government, knowingly presented and/or caused to be presented false or  
15 fraudulent claims for payment or approval under Medicaid and other Illinois state funded  
16 programs to officers, employees or agents of the state within the meaning of 740 Ill.  
17 Comp. Stat. §175/3(a)(1).  
18

19 529. By virtue of the acts described above, defendants, for the purpose of defrauding the  
20 Illinois state government, knowingly made, used and/or caused to be made or used, false  
21 or fraudulent records or statements to get false and fraudulent claims paid or approved  
22 under Medicaid and other Illinois state funded programs to officers, employees or agents  
23 of the state within the meaning of 740 Ill. Comp. Stat. §175/3(a)(1), (2).  
24

25 530. By virtue of the acts described above, defendants knowingly entered into and furthered a  
26 conspiracy to defraud the Illinois state government by knowingly participating in  
27  
28

1 presenting and/or causing to be presented false or fraudulent records or statements to get  
2 false and fraudulent claims paid or approved under Medicaid and other Illinois state  
3 government programs to officers, employees or agents of the state within the meaning of  
4 740 Ill. Comp. Stat. §175/3(a)(2).  
5

6 531. As a result, Illinois state monies were lost through payments made in respect of the  
7 claims and other costs were sustained by the Illinois state government.  
8

9 532. Therefore, the Illinois state government has been damaged in an amount to be proven at  
10 trial. Damages to the state of Illinois include, but are not limited to, three times the full  
11 value of any such fraudulent claims.  
12

13 533. Additionally, the Illinois state government is entitled to the maximum penalty for each  
14 and every false and fraudulent claim made and caused to be made by defendants and  
15 arising from their fraudulent conduct as described herein.  
16

#### 17 COUNT TEN

#### 18 **Indiana False Claims and Whistleblower Protection Act** 19 **IC 5-11-5.5-2(b)(1) and (2)**

20 534. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
21 as set forth fully above.

22 535. This is a claim for penalties and treble damages under the Indiana False Claims and  
23 Whistleblower Protection Act.  
24

25 536. By virtue of the acts described above, defendants, for the purpose of defrauding the  
26 Indiana state government, knowingly presented and/or caused to be presented false or  
27 fraudulent claims for payment or approval under Medicaid and other Indiana state funded  
28

1 programs to officers, employees or agents of the state within the meaning of IC 5-11-5.5-  
2 2(b)(1).

3 537. By virtue of the acts described above, defendants, for the purpose of defrauding the  
4 Indiana state government, knowingly made, used and/or caused to be made or used, false  
5 or fraudulent records or statements to get false and fraudulent claims paid or approved  
6 under Medicaid and other Indiana state funded programs to officers, employees or agents  
7 of the state within the meaning of IC 5-11-5.5-2(b)(1) and (2).  
8  
9

10 538. By virtue of the acts described above, defendants knowingly entered into and furthered a  
11 conspiracy to defraud the Indiana state government by knowingly participating in  
12 presenting and/or causing to be presented false or fraudulent records or statements to get  
13 false and fraudulent claims paid or approved under Medicaid and other Indiana state  
14 government programs to officers, employees or agents of the state within the meaning of  
15 IC 5-11-5.5-2(b)(2).  
16  
17

18 539. As a result, Indiana state monies were lost through payments made in respect of the  
19 claims and other costs were sustained by the Indiana state government.  
20

21 540. Therefore, the Indiana state government has been damaged in an amount to be proven at  
22 trial. Damages to the state of Indiana include, but are not limited to, three times the full  
23 value of any such fraudulent claims.

24 541. Additionally, the Indiana state government is entitled to the maximum penalty for each  
25 and every false and fraudulent claim made and caused to be made by defendants and  
26 arising from their fraudulent conduct as described herein.  
27  
28

**COUNT ELEVEN**

**Louisiana Medical Assistance Programs Integrity Law  
La. Rev. Stat. §437 et. seq.**

542. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

543. This is a claim for penalties and treble damages under the Louisiana Medical Assistance Programs Integrity Law.

544. By virtue of the acts described above, defendants, for the purpose of defrauding the Louisiana state government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Louisiana state funded programs to officers, employees or agents of the state within the meaning of La. Rev. Stat. §437 et seq.

545. By virtue of the acts described above, defendants, for the purpose of defrauding the Louisiana state government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other Louisiana state funded programs to officers, employees or agents of the state within the meaning of La. Rev. Stat. §437 et seq.

546. By virtue of the acts described above, defendants knowingly entered into and furthered a conspiracy to defraud the Louisiana state government by knowingly participating in presenting and/or causing to be presented false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other Louisiana state

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1 government programs to officers, employees or agents of the state within the meaning of  
2 La. Rev. Stat. §437 et seq.

3 547. As a result, Louisiana state monies were lost through payments made in respect of the  
4 claims and other costs were sustained by the Louisiana state government.

5  
6 548. Therefore, the Louisiana state government has been damaged in an amount to be proven  
7 at trial. Damages to the state of Louisiana include, but are not limited to, three times the  
8 full value of any such fraudulent claims.

9  
10 549. Additionally, the Louisiana state government is entitled to the maximum penalty for each  
11 and every false and fraudulent claim made and caused to be made by defendants and  
12 arising from their fraudulent conduct as described herein.

13  
14 **COUNT TWELVE**

15 **Massachusetts False Claims Law**  
16 **Mass. Gen. Laws ch. 12 §5B(1), (2)**

17 550. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
18 as set forth fully above.

19  
20 551. This is a claim for penalties and treble damages under the Massachusetts False Claims  
21 Law.

22 552. By virtue of the acts described above, defendants, for the purpose of defrauding the  
23 Massachusetts state government, knowingly presented and/or caused to be presented false  
24 or fraudulent claims for payment or approval under Medicaid and other Massachusetts  
25 state funded programs to officers, employees or agents of the state within the meaning of  
26 Mass. Gen. Laws ch. 12 §5b(1).  
27  
28

1 553. By virtue of the acts described above, defendants, for the purpose of defrauding the  
2 Massachusetts state government, knowingly made, used and/or caused to be made or  
3 used, false or fraudulent records or statements to get false and fraudulent claims paid or  
4 approved under Medicaid and other Massachusetts state funded programs to officers,  
5 employees or agents of the state within the meaning of Mass. Gen. Laws ch. 12 §5b(1),  
6 (2).  
7

8 554. By virtue of the acts described above, defendants knowingly entered into and furthered a  
9 conspiracy to defraud the Massachusetts state government by knowingly participating in  
10 presenting and/or causing to be presented false or fraudulent records or statements to get  
11 false and fraudulent claims paid or approved under Medicaid and other Massachusetts  
12 state government programs to officers, employees or agents of the state within the  
13 meaning of Mass. Gen. Laws ch. 12 §5b(2).  
14

15 555. As a result, Massachusetts state monies were lost through payments made in respect of  
16 the claims and other costs were sustained by the Massachusetts state government.  
17

18 556. Therefore, the Massachusetts state government has been damaged in an amount to be  
19 proven at trial. Damages to the state of Massachusetts include, but are not limited to,  
20 three times the full value of any such fraudulent claims.  
21

22 557. Additionally, the Massachusetts state government is entitled to the maximum penalty for  
23 each and every false and fraudulent claim made and caused to be made by defendants and  
24 arising from their fraudulent conduct as described herein.  
25  
26  
27  
28

**COUNT THIRTEEN**

**Michigan Medicaid False Claims Act  
Mich. Public Act 337**

558. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

559. This is a claim for penalties and treble damages under the Michigan Medicaid False Claims Act.

560. By virtue of the acts described above, defendants, for the purpose of defrauding the Michigan state government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Michigan and other state funded programs to officers, employees or agents of the state within the meaning of Mich. Public Act 337.

561. By virtue of the acts described above, defendants, for the purpose of defrauding the Michigan state government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other Michigan state funded programs to officers, employees or agents of the state within the meaning of Mich. Public Act 337.

562. By virtue of the acts described above, defendants knowingly entered into and furthered a conspiracy to defraud the Michigan state government by knowingly participating in presenting and/or causing to be presented false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other Michigan state

1 government programs to officers, employees or agents of the state within the meaning of  
2 Mich. Public Act 337.

3 563. As a result, Michigan state monies were lost through payments made in respect of the  
4 claims and other costs were sustained by the Michigan state government.

5  
6 564. Therefore, the Michigan state government has been damaged in an amount to be proven  
7 at trial. Damages to the state of Michigan include, but are not limited to, three times the  
8 full value of any such fraudulent claims.

9  
10 565. Additionally, the Michigan state government is entitled to the maximum penalty for each  
11 and every false and fraudulent claim made and caused to be made by defendants and  
12 arising from their fraudulent conduct as described herein.  
13

14 **COUNT FOURTEEN**

15 **Montana False Claims Act**  
16 **Mont. Gen. Laws 17-8-403 (1)(a) and (b)**

17 566. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
18 as set forth fully above.

19 567. This is a claim for penalties and treble damages under the Montana False Claims Act.  
20

21 568. By virtue of the acts described above, defendants, for the purpose of defrauding the  
22 Montana state government, knowingly presented and/or caused to be presented false or  
23 fraudulent claims for payment or approval under Medicaid and other Montana state  
24 funded programs to officers, employees or agents of the state within the meaning of  
25 Mont. Gen. Laws 17-8-403 (1)(a).  
26  
27  
28

1 569. By virtue of the acts described above, defendants, for the purpose of defrauding the  
2 Montana state government, knowingly made, used and/or caused to be made or used,  
3 false or fraudulent records or statements to get false and fraudulent claims paid or  
4 approved under Medicaid and other Montana state funded programs to officers,  
5 employees or agents of the state within the meaning of Mont. Gen. Laws 17-8-403 (1)(a)  
6 and (b).  
7

8  
9 570. By virtue of the acts described above, defendants knowingly entered into and furthered a  
10 conspiracy to defraud the Montana state government by knowingly participating in  
11 presenting and/or causing to be presented false or fraudulent records or statements to get  
12 false and fraudulent claims paid or approved under Medicaid and other Montana state  
13 government programs to officers, employees or agents of the state within the meaning of  
14 Mont. Gen. Laws 17-8-403 (1)(b).  
15

16 571. As a result, Montana state monies were lost through payments made in respect of the  
17 claims and other costs were sustained by the Montana state government.  
18

19 572. Therefore, the Montana state government has been damaged in an amount to be proven at  
20 trial. Damages to the state of Montana include, but are not limited to, three times the full  
21 value of any such fraudulent claims.  
22

23 573. Additionally, the Montana state government is entitled to the maximum penalty for each  
24 and every false and fraudulent claim made and caused to be made by defendants and  
25 arising from their fraudulent conduct as described herein.  
26  
27  
28

**COUNT FIFTEEN**

**New York False Claims Act  
N.Y. State Fin. §187 et seq.**

574. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

575. This is a claim for penalties and treble damages under the New York False Claims Act.

576. By virtue of the acts described above, defendants, for the purpose of defrauding the New York state government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other New York state funded programs to officers, employees or agents of the state within the meaning of N.Y. State Fin. §187 et seq.

577. By virtue of the acts described above, defendants, for the purpose of defrauding the New York state government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other New York state funded programs to officers, employees or agents of the state within the meaning of N.Y. State Fin. §187 et seq.

578. By virtue of the acts described above, defendants knowingly entered into and furthered a conspiracy to defraud the New York state government by knowingly participating in presenting and/or causing to be presented false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other New York state

government programs to officers, employees or agents of the state within the meaning of N.Y. State Fin. §187 et seq.

579. As a result, New York state monies were lost through payments made in respect of the claims and other costs were sustained by the New York state government.

580. Therefore, the New York state government has been damaged in an amount to be proven at trial. Damages to the state of New York include, but are not limited to, three times the full value of any such fraudulent claims.

581. Additionally, the New York state government is entitled to the maximum penalty for each and every false and fraudulent claim made and caused to be made by defendants and arising from their fraudulent conduct as described herein.

#### **COUNT SIXTEEN**

##### **Nevada False Claims Act Nev. Rev. Stat. Ann. §357.040(1)(a), (b)**

582. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

583. This is a claim for penalties and treble damages under the Nevada False Claims Act.

584. By virtue of the acts described above, defendants, for the purpose of defrauding the Nevada state government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Nevada state funded programs to officers, employees or agents of the state within the meaning of Nev. Rev. Stat. Ann. §357.040(1)(a).

1 585. By virtue of the acts described above, defendants, for the purpose of defrauding the  
2 Nevada state government, knowingly made, used and/or caused to be made or used, false  
3 or fraudulent records or statements to get false and fraudulent claims paid or approved  
4 under Medicaid and other Nevada state funded programs to officers, employees or agents  
5 of the state within the meaning of Nev. Rev. Stat. Ann. §357.040(1)(a), (b).  
6

7 586. By virtue of the acts described above, defendants knowingly entered into and furthered a  
8 conspiracy to defraud the Nevada state government by knowingly participating in  
9 presenting and/or causing to be presented false or fraudulent records or statements to get  
10 false and fraudulent claims paid or approved under Medicaid and other Nevada state  
11 government programs to officers, employees or agents of the state within the meaning of  
12 Nev. Rev. Stat. Ann. §357.040(1)(b).  
13  
14

15 587. As a result, Nevada state monies were lost through payments made in respect of the  
16 claims and other costs were sustained by the Nevada state government.  
17

18 588. Therefore, the Nevada state government has been damaged in an amount to be proven at  
19 trial. Damages to the state of Nevada include, but are not limited to, three times the full  
20 value of any such fraudulent claims.  
21

22 589. Additionally, the Nevada state government is entitled to the maximum penalty for each  
23 and every false and fraudulent claim made and caused to be made by defendants and  
24 arising from their fraudulent conduct as described herein.  
25  
26  
27  
28

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**COUNT SEVENTEEN**

**New Hampshire False Claims Act  
N.H. Rev. Stat. Ann. §167:61-b(1)(a), (b), and (e)**

590. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

591. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.

592. By virtue of the acts described above, defendants, for the purpose of defrauding the New Hampshire state government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other New Hampshire state funded programs to officers, employees or agents of the state within the meaning of N.H. Rev. Stat. Ann. §167:61-b(1)(a).

593. By virtue of the acts described above, defendants, for the purpose of defrauding the New Hampshire state government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other New Hampshire state funded programs to officers, employees or agents of the state within the meaning of N.H. Rev. Stat. Ann. §167:61-b(1)(a), (b).

594. By virtue of the acts described above, defendants knowingly entered into and furthered a conspiracy to defraud the New Hampshire state government by knowingly participating in presenting and/or causing to be presented false or fraudulent records or statements to

1 get false and fraudulent claims paid or approved under Medicaid and other New  
2 Hampshire state government programs to officers, employees or agents of the state within  
3 the meaning of N.H. Rev. Stat. Ann. §167:61-b(1)(b).

4  
5 595. As a result, New Hampshire state monies were lost through payments made in respect of  
6 the claims and other costs were sustained by the New Hampshire state government.

7 596. Therefore, the New Hampshire state government has been damaged in an amount to be  
8 proven at trial. Damages to the state of New Hampshire include, but are not limited to,  
9 three times the full value of any such fraudulent claims.

10  
11 597. Additionally, the New Hampshire state government is entitled to the maximum penalty  
12 for each and every false and fraudulent claim made and caused to be made by defendants  
13 and arising from their fraudulent conduct as described herein.  
14

15 **COUNT EIGHTEEN**

16 **New Jersey False Claims Act**  
17 **N.J. Stat. 2A:32C-1 et seq.**

18 598. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
19 as set forth fully above.

20  
21 599. This is a claim for penalties and treble damages under the New Jersey False Claims Act.

22 600. By virtue of the acts described above, defendants, for the purpose of defrauding the New  
23 Jersey state government, knowingly presented and/or caused to be presented false or  
24 fraudulent claims for payment or approval under Medicaid and other New Jersey state  
25 funded programs to officers, employees or agents of the state within the meaning of N.J.  
26 Stat. 2a:32c-1 et seq.  
27  
28

1 601. By virtue of the acts described above, defendants, for the purpose of defrauding the New  
2 Jersey state government, knowingly made, used and/or caused to be made or used, false  
3 or fraudulent records or statements to get false and fraudulent claims paid or approved  
4 under Medicaid and other New Jersey state funded programs to officers, employees or  
5 agents of the state within the meaning of N.J. Stat. 2a:32c-1 et seq.  
6

7 602. By virtue of the acts described above, defendants knowingly entered into and furthered a  
8 conspiracy to defraud the New Jersey state government by knowingly participating in  
9 presenting and/or causing to be presented false or fraudulent records or statements to get  
10 false and fraudulent claims paid or approved under Medicaid and other New Jersey state  
11 government programs to officers, employees or agents of the state within the meaning of  
12 N.J. Stat. 2a:32c-1 et seq.  
13  
14

15 603. As a result, New Jersey state monies were lost through payments made in respect of the  
16 claims and other costs were sustained by the New Jersey state government.  
17

18 604. Therefore, the New Jersey state government has been damaged in an amount to be proven  
19 at trial. Damages to the state of New Jersey include, but are not limited to, three times  
20 the full value of any such fraudulent claims.  
21

22 605. Additionally, the New Jersey state government is entitled to the maximum penalty for  
23 each and every false and fraudulent claim made and caused to be made by defendants and  
24 arising from their fraudulent conduct as described herein.  
25  
26  
27  
28

**COUNT NINETEEN**

**New Mexico Medicaid False Claims Act  
N.M. Stat. Ann. § 27-2F-1 et seq.**

606. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

607. This is a claim for penalties and treble damages under the New Mexico False Claims Act.

608. By virtue of the acts described above, defendants, for the purpose of defrauding the New Mexico state government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other New Mexico state funded programs to officers, employees or agents of the state within the meaning of N.M. Stat. Ann. § 27-2f-1 et seq.

609. By virtue of the acts described above, defendants, for the purpose of defrauding the New Mexico state government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other New Mexico state funded programs to officers, employees or agents of the state within the meaning of N.M. Stat. Ann. § 27-2f-1 et seq.

610. By virtue of the acts described above, defendants knowingly entered into and furthered a conspiracy to defraud the New Mexico state government by knowingly participating in presenting and/or causing to be presented false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other New Mexico state

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government programs to officers, employees or agents of the state within the meaning of N.M. Stat. Ann. § 27-2f-1 et seq.

611. As a result, New Mexico state monies were lost through payments made in respect of the claims and other costs were sustained by the New Mexico state government.

612. Therefore, the New Mexico state government has been damaged in an amount to be proven at trial. Damages to the state of New Mexico include, but are not limited to, three times the full value of any such fraudulent claims.

613. Additionally, the New Mexico state government is entitled to the maximum penalty for each and every false and fraudulent claim made and caused to be made by defendants and arising from their fraudulent conduct as described herein.

#### **COUNT TWENTY**

##### **Oklahoma Medicaid False Claims Act Okla. Stat. tit. 63 §5053 et seq.**

614. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

615. This is a claim for penalties and treble damages under the Oklahoma Medicaid False Claims Act.

616. By virtue of the acts described above, defendants, for the purpose of defrauding the Oklahoma state government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under the Oklahoma Medicaid program to officers, employees or agents of the state within the meaning of Okla. Stat. Tit. 63 §5053 et seq.

1 617. By virtue of the acts described above, defendants, for the purpose of defrauding the  
2 Oklahoma state government, knowingly made, used and/or caused to be made or used,  
3 false or fraudulent records or statements to get false and fraudulent claims paid or  
4 approved under the Oklahoma Medicaid program to officers, employees or agents of the  
5 state within the meaning of Okla. Stat. Tit. 63 §5053 et seq.  
6

7 618. By virtue of the acts described above, defendants knowingly entered into and furthered a  
8 conspiracy to defraud the Oklahoma state government by knowingly participating in  
9 presenting and/or causing to be presented false or fraudulent records or statements to get  
10 false and fraudulent claims paid or approved under the Oklahoma Medicaid program to  
11 officers, employees or agents of the state within the meaning of Okla. Stat. Tit. 63 §5053  
12 et seq.  
13  
14

15 619. As a result, Oklahoma state monies were lost through payments made in respect of the  
16 claims and other costs were sustained by the Oklahoma state government.  
17

18 620. Therefore, the Oklahoma state government has been damaged in an amount to be proven  
19 at trial. Damages to the state of Oklahoma include, but are not limited to, three times the  
20 full value of any such fraudulent claims.  
21

22 621. Additionally, the Oklahoma state government is entitled to the maximum penalty for each  
23 and every false and fraudulent claim made and caused to be made by defendants and  
24 arising from their fraudulent conduct as described herein.  
25  
26  
27  
28

**COUNT TWENTY ONE**

**Rhode Island False Claim Act  
R.I. Gen. Laws 9-1.1-3 et seq.**

622. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

623. This is a claim for penalties and treble damages under the Rhode Island False Claims Act.

624. By virtue of the acts described above, defendants, for the purpose of defrauding the Rhode Island state government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Rhode Island state funded programs to officers, employees or agents of the state within the meaning of R.I. Gen. Laws 9-1.1-3 et seq.

625. By virtue of the acts described above, defendants, for the purpose of defrauding the Rhode Island state government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other Rhode Island state funded programs to officers, employees or agents of the state within the meaning of R.I. Gen. Laws 9-1.1-3 et seq.

626. By virtue of the acts described above, defendants knowingly entered into and furthered a conspiracy to defraud the Rhode Island state government by knowingly participating in presenting and/or causing to be presented false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other Rhode Island state funded programs to officers, employees or agents of the state within the meaning of R.I. Gen. Laws 9-1.1-3 et seq.

1 627. As a result, Rhode Island state monies were lost through payments made in respect of the  
2 claims and other costs were sustained by the Rhode Island state government.

3 628. Therefore, the Rhode Island state government has been damaged in an amount to be  
4 proven at trial. Damages to the state of Rhode Island include, but are not limited to, three  
5 times the full value of any such fraudulent claims.  
6

7 629. Additionally, the Rhode Island state government is entitled to the maximum penalty for  
8 each and every false and fraudulent claim made and caused to be made by defendants and  
9 arising from their fraudulent conduct as described herein.  
10

11 **COUNT TWENTY TWO**

12 **Tennessee Medicaid False Claims Act**  
13 **Tenn. Code Ann. §71-5-182(a)(1) and (2)**

14 630. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
15 as set forth fully above.  
16

17 631. This is a claim for penalties and treble damages under the Tennessee Medicaid False  
18 Claims Act.  
19

20 632. By virtue of the acts described above, defendants, for the purpose of defrauding the  
21 Tennessee state government, knowingly presented and/or caused to be presented false or  
22 fraudulent claims for payment or approval under the Tennessee Medicaid program to  
23 officers, employees or agents of the state within the meaning of Tenn. Code Ann. §71-5-  
24 182(a)(1).  
25

26 633. By virtue of the acts described above, defendants, for the purpose of defrauding the  
27 Tennessee state government, knowingly made, used and/or caused to be made or used,  
28

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1 false or fraudulent records or statements to get false and fraudulent claims paid or  
2 approved under the Tennessee Medicaid program to officers, employees or agents of the  
3 state within the meaning of Tenn. Code Ann. §71-5-182(a)(1), (2).

4  
5 634. By virtue of the acts described above, defendants knowingly entered into and furthered a  
6 conspiracy to defraud the Tennessee state government by knowingly participating in  
7 presenting and/or causing to be presented false or fraudulent records or statements to get  
8 false and fraudulent claims paid or approved under the Tennessee Medicaid program to  
9 officers, employees or agents of the state within the meaning of Tenn. Code Ann. §71-5-  
10 182(a)(2).

11  
12 635. As a result, Tennessee state monies were lost through payments made in respect of the  
13 claims and other costs were sustained by the Tennessee state government.

14  
15 636. Therefore, the Tennessee state government has been damaged in an amount to be proven  
16 at trial. Damages to the state of Tennessee include, but are not limited to, three times the  
17 full value of any such fraudulent claims.

18  
19 637. Additionally, the Tennessee state government is entitled to the maximum penalty for each  
20 and every false and fraudulent claim made and caused to be made by defendants and  
21 arising from their fraudulent conduct as described herein.

22  
23 **COUNT TWENTY THREE**

24 **Virginia Fraud Against Taxpayers Act**  
25 **Va. Code Ann. §8.01-216.3(a)(1), (2)**

26 638. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
27 as set forth fully above.  
28

1 639. This is a claim for penalties and treble damages under the Virginia Fraud Against  
2 Taxpayers Act.

3 640. By virtue of the acts described above, defendants, for the purpose of defrauding the  
4 Virginia state government, knowingly presented and/or caused to be presented false or  
5 fraudulent claims for payment or approval under Medicaid and other Virginia state  
6 funded programs to officers, employees or agents of the state within the meaning of Va.  
7 Code Ann. §8.01-216.3(a)(1).  
8  
9

10 641. By virtue of the acts described above, defendants, for the purpose of defrauding the  
11 Virginia state government, knowingly made, used and/or caused to be made or used, false  
12 or fraudulent records or statements to get false and fraudulent claims paid or approved  
13 under Medicaid and other Virginia state funded programs to officers, employees or  
14 agents of the state within the meaning of Va. Code Ann. §8.01-216.3(a)(1), (2).  
15

16 642. By virtue of the acts described above, defendants knowingly entered into and furthered a  
17 conspiracy to defraud the Virginia state government by knowingly participating in  
18 presenting and/or causing to be presented false or fraudulent records or statements to get  
19 false and fraudulent claims paid or approved under Medicaid and other Virginia state  
20 funded programs to officers, employees or agents of the state within the meaning of Va.  
21 Code Ann. §8.01-216.3(a)(2).  
22  
23

24 643. As a result, Virginia state monies were lost through payments made in respect of the  
25 claims and other costs were sustained by the Virginia state government.  
26  
27  
28

1 644. Therefore, the Virginia state government has been damaged in an amount to be proven at  
2 trial. Damages to the state of Virginia include, but are not limited to, three times the full  
3 value of any such fraudulent claims.

4 645. Additionally, the Virginia state government is entitled to the maximum penalty for each  
5 and every false and fraudulent claim made and caused to be made by defendants and  
6 arising from their fraudulent conduct as described herein.  
7

8 **COUNT TWENTY FOUR**  
9

10 **Wisconsin False Claims for Medical Assistance Law**  
11 **Wis. Stat. § 20.931 et seq.**

12 646. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
13 as set forth fully above.

14 647. This is a claim for penalties and treble damages under the Wisconsin False Claims for  
15 Medical Assistance Law.  
16

17 648. By virtue of the acts described above, defendants, for the purpose of defrauding the  
18 Wisconsin state government, knowingly presented and/or caused to be presented false or  
19 fraudulent claims for payment or approval under Medicaid and other Wisconsin state  
20 funded programs to officers, employees or agents of the state within the meaning of Wis.  
21 Stat. § 20.931.  
22

23 649. By virtue of the acts described above, defendants, for the purpose of defrauding the  
24 Wisconsin state government, knowingly made, used and/or caused to be made or used,  
25 false or fraudulent records or statements to get false and fraudulent claims paid or  
26  
27  
28

1 approved under Medicaid and other Wisconsin state funded programs to officers,  
2 employees or agents of the state within the meaning of Wis. Stat. § 20.931.

3 650. By virtue of the acts described above, defendants knowingly entered into and furthered a  
4 conspiracy to defraud the Wisconsin state government by knowingly participating in  
5 presenting and/or causing to be presented false or fraudulent records or statements to get  
6 false and fraudulent claims paid or approved under Medicaid and other Wisconsin state  
7 funded programs to officers, employees or agents of the state within the meaning of Wis.  
8 Stat. § 20.931.  
9

10  
11 651. As a result, Wisconsin state monies were lost through payments made in respect of the  
12 claims and other costs were sustained by the Wisconsin state government.

13  
14 652. Therefore, the Wisconsin state government has been damaged in an amount to be proven  
15 at trial. Damages to the state of Wisconsin include, but are not limited to, three times the  
16 full value of any such fraudulent claims.  
17

18 653. Additionally, the Wisconsin state government is entitled to the maximum penalty for  
19 each and every false and fraudulent claim made and caused to be made by defendants and  
20 arising from their fraudulent conduct as described herein.  
21

22 **COUNT TWENTY FIVE**

23 **New York City False Claims Act**  
24 **Municipal Code, tit. 7, ch. 8 §§ 7-801 et seq.**

25 654. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
26 as set forth fully above.

27 655. This is a claim for penalties and treble damages under the New York False Claims Act.  
28

1 656. By virtue of the acts described above, defendants, for the purpose of defrauding the New  
2 York city government, knowingly presented and/or caused to be presented false or  
3 fraudulent claims for payment or approval under Medicaid and other New York city  
4 funded programs to officers, employees or agents of the state within the meaning of  
5 Municipal Code, tit. 7, ch. 8 §§ 7-801 et seq.  
6

7 657. By virtue of the acts described above, defendants, for the purpose of defrauding the New  
8 York city government, knowingly made, used and/or caused to be made or used, false or  
9 fraudulent records or statements to get false and fraudulent claims paid or approved under  
10 Medicaid and other New York city funded programs to officers, employees or agents of  
11 the state within the meaning of Municipal Code, tit. 7, ch. 8 §§ 7-801 et seq.  
12

13 658. By virtue of the acts described above, defendants knowingly entered into and furthered a  
14 conspiracy to defraud the New York city government by knowingly participating in  
15 presenting and/or causing to be presented false or fraudulent records or statements to get  
16 false and fraudulent claims paid or approved under Medicaid and other New York city  
17 funded programs to officers, employees or agents of the state within the meaning of  
18 Municipal Code, tit. 7, ch. 8 §§ 7-801 et seq.  
19

20 659. As a result, New York city monies were lost through payments made in respect of the  
21 claims and other costs were sustained by the New York city government.  
22

23 660. Therefore, the New York city government has been damaged in an amount to be proven  
24 at trial. Damages to the city of New York include, but are not limited to, three times the  
25 full value of any such fraudulent claims.  
26  
27  
28

661. Additionally, the New York city government is entitled to the maximum penalty for each and every false and fraudulent claim made and caused to be made by defendants and arising from their fraudulent conduct as described herein.

**COUNT TWENTY SIX**

**Chicago False Claims Act  
Municipal Code, tit. 1, ch. 1-21 et seq.**

662. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

663. This is a claim for penalties and treble damages under the Chicago False Claims Act.

664. By virtue of the acts described above, defendants, for the purpose of defrauding the Chicago government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Chicago funded programs to officers, employees or agents of the state within the meaning of Municipal Code, tit. 1, ch. 1-21 et seq.

665. By virtue of the acts described above, defendants, for the purpose of defrauding the Chicago government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicaid and other Chicago funded programs to officers, employees or agents of the state within the meaning of Municipal Code, tit. 1, ch. 1-21 et seq.

666. By virtue of the acts described above, defendants knowingly entered into and furthered a conspiracy to defraud the Chicago government by knowingly participating in presenting and/or causing to be presented false or fraudulent records or statements to get false and

1 fraudulent claims paid or approved under Medicaid and other Chicago funded programs  
 2 to officers, employees or agents of the state within the meaning of municipal code, tit. 1,  
 3 ch. 1-21 et seq.

4  
 5 667. As a result, Chicago monies were lost through payments made in respect of the claims  
 6 and other costs were sustained by the Chicago government.

7 668. Therefore, the Chicago government has been damaged in an amount to be proven at trial.  
 8 Damages to the city of Chicago include, but are not limited to, three times the full value  
 9 of any such fraudulent claims.

10  
 11 669. Additionally, the Chicago government is entitled to the maximum penalty for each and  
 12 every false and fraudulent claim made and caused to be made by defendants and arising  
 13 from their fraudulent conduct as described herein.  
 14

### 15 COUNT TWENTY SEVEN

#### 16 **District of Columbia Procurement Reform Amendment Act** 17 **D.C. Code Ann. §1-1188.14(a)(1), (2)**

18 670. Plaintiffs/Relators incorporate the allegations contained herein and hereby reallege them  
 19 as set forth fully above.

20  
 21 671. This is a claim for penalties and treble damages under the District of Columbia  
 22 Procurement Reform Amendment Act.

23 672. By virtue of the acts described above, defendants, for the purpose of defrauding the  
 24 District of Columbia government, knowingly presented and/or caused to be presented  
 25 false or fraudulent claims for payment or approval under Medicaid and other District of  
 26  
 27  
 28

1 Columbia funded programs to officers, employees or agents of the state within the  
2 meaning of D.C. Code Ann. §1-1188.14(a)(1).

3 673. By virtue of the acts described above, defendants, for the purpose of defrauding the  
4 District of Columbia government, knowingly made, used and/or caused to be made or  
5 used, false or fraudulent records or statements to get false and fraudulent claims paid or  
6 approved under Medicaid and other District of Columbia funded programs to officers,  
7 employees or agents of the state within the meaning of D.C. Code Ann. §1-1188.14(a)(1),  
8 (2).  
9

10  
11 674. By virtue of the acts described above, defendants knowingly entered into and furthered a  
12 conspiracy to defraud the District of Columbia government by knowingly participating in  
13 presenting and/or causing to be presented false or fraudulent records or statements to get  
14 false and fraudulent claims paid or approved under Medicaid and other District of  
15 Columbia funded programs to officers, employees or agents of the state within the  
16 meaning of D.C. Code Ann. §1-1188.14(a)(2).  
17

18  
19 675. As a result, District of Columbia monies were lost through payments made in respect of  
20 the claims and other costs were sustained by the District of Columbia government.  
21

22 676. Therefore, the District of Columbia government has been damaged in an amount to be  
23 proven at trial. Damages to the District of Columbia include, but are not limited to, three  
24 times the full value of any such fraudulent claims.  
25  
26  
27  
28

677. Additionally, the District of Columbia government is entitled to the maximum penalty for each and every false and fraudulent claim made and caused to be made by defendants and arising from their fraudulent conduct as described herein.

### **COUNT TWENTY EIGHT**

#### **Retaliation/Termination in Violation of the False Claims Act (Plaintiff-Relator Jeff Campie against Defendant Gilead Sciences, Inc.) (31 U.S.C. § 3730 (h))**

678. Plaintiff-Relator Jeff Campie repeats and realleges each and every allegation above as though fully set forth herein.

679. Relator Jeff Campie began working for Gilead in or about July 2006 as the Senior Director of Global Quality Assurance. Prior to his employment with Gilead, Mr. Campie had more than 17 years of experience in compliance and quality assurance in the pharmaceutical industry.

680. Beginning in or about July 2006, and throughout his employment with Gilead, Relator Jeff Campie spoke to Gilead's top executives, including but not limited to: Tony Caracciolo (his manager and SVP / Manufacturing and Operations), Ron Branning (Chief Compliance Officer), Tom Weber (Vice President ), Tammis Matzinger (Vice President), John Milligan (Chief Operating Officer), Gregg Alton (Senior Council), and T. Yang (SVP / Pharmaceutical Manufacturing and Development), on numerous occasions about concerns he had with and objections to the manufacturing and compliance-related practices described above. For those products about which Relator Jeff Campie raised concerns and objected to various manufacturing practices and GMP concerns to which

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1 Gilead had a contract(s) with the United States government to sell such products to the  
2 United States, Relator Jeff Campie knew these practices to effect fraud on the  
3 government based on his understanding of the US GMP requirements and by the fact that  
4 he was the Gilead quality signatory on all Gilead quality (supply) agreements – including  
5 those contracts entered into with the us government. Accordingly, he was aware for an  
6 extended period of time that Gilead knowingly delivered or caused to be delivered  
7 misbranded and adulterated products to the U.S. government as a result of distributing  
8 drugs containing contaminants, adulterants, or otherwise did not meet the conditions by  
9 which FDA approval had been granted.  
10  
11

12 681. On an ongoing basis Relator Jeff Campie raised concerns about and objections to  
13 Gilead's practices and in response to his having raised such concerns and objections,  
14 Caracciolo and Branning, among others at Gilead, engaged in ongoing retaliation toward  
15 him, including, but not limited to, ostracizing Relator Jeff Campie, threatening to  
16 terminate his employment in approximately mid-January 2009, and ultimately  
17 terminating his employment in July 2009.  
18  
19

20 682. Relator Jeff Campie objected on numerous occasions to Gilead's practices as alleged:  
21 using the IND designation to import API material through Gilead Alberta, Canada, that  
22 was then manufactured into a finished drug product in Canada, and brought to the United  
23 States for packaging and commercial distribution, including numerous sales to the federal  
24 government; defrauding the federal government by knowingly presenting, and causing  
25 others to present, false claims for unapproved drug products; selling to the federal  
26  
27  
28

1 government drug products that were known to be adulterated due to exposure to  
2 temperatures outside of the labeled and approved storage conditions during shipment and  
3 transit; knowingly falsifying and omitting information on new drug applications to  
4 fraudulently gain FDA approval to market drugs; knowingly falsifying API and drug  
5 product COAs associated with Gilead drug products that are then sold to the federal  
6 government; intentionally minimizing the presence of adulterants and extraneous  
7 substances found in API and drug products, and justifying these adulterants as "aesthetic  
8 defects" thereby willfully misbranding such products sold to the federal government;  
9 knowingly supplying adulterated placebo and drug products contaminated with filth,  
10 teflon, metal particles - including metal wires, cadmium, food grade oil, acetaminophen,  
11 stainless steel and elevated process impurities to federally sponsored human drug trials  
12 involving HIV-positive pregnant women, newborns, infants and adolescent children;  
13 falsifying study data within the context of regulatory submissions to gain expanded  
14 therapeutic indications, increased patient populations and patent extensions - resulting in  
15 higher revenues for the company via government reimbursement programs; defrauding  
16 the federal government by knowingly manufacturing, distributing and selling  
17 microbially-tainted HIV drugs; selling adulterated drugs to the federal government by  
18 knowingly altering approved drug substance specifications, manufacturing processes and  
19 processing equipment without obtaining or waiting for prior FDA approval as mandated  
20 by the FDA regulations; manipulating information and sharing incomplete information  
21 with the FDA in regulatory registration documents; and deliberately using unapproved  
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1 APIs in adulterating FDA-approved drug products subsequently placed into interstate  
2 commerce and sold to the United States government.

3 683. Relator Jeff Campie reasonably believed that the practices to which he objected and  
4 about which he complained, as alleged herein, effected a fraud on the United States  
5 government, the largest purchasers of Gilead's drug products.

6  
7 684. After Relator Jeff Campie complained about and formally objected to Gilead's practices  
8 detailed herein and in response to such complaints and objections, Gilead subjected  
9 Relator Jeff Campie to ongoing retaliation, including, but not limited to, ostracism, the  
10 threat of termination, and ultimately terminating his of employment on July 15, 2009 by  
11 publishing an announcement to company employees falsely claiming that Relator Jeff  
12 Campie had resigned.  
13

14  
15 685. Gilead retaliated against Relator Jeff Campie in this manner because of his opposition  
16 and objections to Gilead's unlawful practices as described herein.  
17

18 686. Gilead's conduct as alleged herein violated 31 U.S.C. § 3730(h).

19 687. As a direct and proximate result of the above-referenced intentional and willful conduct,  
20 Relator Jeff Campie suffered damages in an amount to be determined at trial, including,  
21 but are not limited to, actual pecuniary damages and actual non-pecuniary damages in the  
22 form of injury to reputation, embarrassment, humiliation, anxiety, physical upset,  
23 emotional upset, mental anguish, physical pain and suffering, damage to career and  
24 professional reputation, back pay and benefits, interest on the back pay and benefits,  
25 future pay and benefits, compensatory damages, and all damages permitted by law,  
26  
27  
28

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1 including but not limited to any punitive and double or treble damages, fees and costs.

2 Relators' damages are continuing and ongoing. Relator is also entitled to reinstatement.

3 688. As a direct and proximate result of Gilead's unlawful conduct, Campie has incurred and  
4 will continue to incur damages in an amount to be proven at trial.  
5

6 **COUNT TWENTY NINE**

7 **Termination in Violation of California Public Policy**  
8 **(Plaintiff-Relator Jeff Campie against Defendant Gilead Sciences, Inc.)**

9 689. Plaintiff-Relator Jeff Campie repeats and realleges each and every allegation above as  
10 though fully set forth herein.  
11

12 690. As detailed above, Relator Jeff Campie objected on numerous occasions to the practices  
13 detailed in this complaint, including but not limited to: using the IND designation to  
14 import API material through Gilead Alberta, Canada, that was then manufactured into a  
15 finished drug product in Canada, and brought to the United States for packaging and  
16 commercial distribution, including numerous sales to the federal government; defrauding  
17 the federal government by knowingly presenting, and causing others to present, false  
18 claims for unapproved drug products; selling to the federal government drug products  
19 that were known to be adulterated due to exposure to temperatures outside of the labeled  
20 and approved storage conditions during shipment and transit; knowingly falsifying and  
21 omitting information on new drug applications to fraudulently gain FDA approval to  
22 market drugs; knowingly falsifying API and drug product COAs associated with Gilead  
23 drug products that are then sold to the federal government; intentionally minimizing the  
24 presence of adulterants and extraneous substances found in API and drug products, and  
25  
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28

1 justifying these adulterants as "aesthetic defects" thereby willfully misbranding such  
2 products sold to the federal government; knowingly supplying adulterated placebo and  
3 drug products contaminated with filth, teflon, metal particles - including metal wires,  
4 cadmium, food grade oil, acetaminophen, stainless steel and elevated process impurities  
5 to federally sponsored human drug trials involving HIV- positive pregnant women,  
6 newborns, infants and adolescent children; falsifying study data within the context of  
7 regulatory submissions to gain expanded therapeutic indications, increased patient  
8 populations and patent extensions - resulting in higher revenues for the company via  
9 government reimbursement programs; defrauding the federal government by  
10 knowingly manufacturing, distributing and selling microbially- tainted HIV drugs; selling  
11 adulterated drugs to the federal government by knowingly altering approved drug  
12 substance specifications, manufacturing processes and processing equipment without  
13 obtaining or waiting for prior FDA approval as mandated by the FDA regulations;  
14 manipulating information and sharing incomplete information with the FDA in  
15 regulatory registration documents; and deliberately using unapproved API's in  
16 adulterating FDA-approved drug products subsequently placed into interstate commerce  
17 and sold to the United States government. Campie reasonably and in good faith  
18 believed such practices were unlawful and in violation of established and relevant  
19 sections of the U.S. Code of Federal Regulations, the Food, Drug, and Cosmetic Act,  
20 conditions contained within the FDA NDA approval letters received by the company, and  
21 cGMPs.  
22  
23  
24  
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691. After Relator Jeff Campie complained about and objected to Gilead's practices detailed herein and in response to such complaints and objections, Gilead subjected him to ongoing retaliation, including, but not limited to, ostracism, the threat of termination, and actual termination of employment. In doing so, Gilead violated the fundamental, substantial, and well-established public policy of the state of California.

692. In taking the actions alleged herein, Gilead acted with malice, fraud and oppression, and in reckless disregard of Relator Jeff Campie's rights, entitling him to an award of punitive damages.

693. As a direct and proximate result of Gilead's unlawful conduct, Relator Jeff Campie has incurred and will continue to incur damages in an amount to be proven at trial.

### **COUNT THIRTY**

#### **Violation of Cal. Lab. Code § 1102.5 *et seq.* (Plaintiff-Relator Jeff Campie against Defendant Gilead Sciences, Inc.)**

694. Plaintiff-Relator Jeff Campie incorporates the allegations contained herein and hereby realleges them as set forth fully above.

695. In violation of Cal. Lab. Code § 1102.5, Defendant, by and through their principals, agents and employees, retaliated against Plaintiff-Relator Jeff Campie for having opposed, resisted, and complained of the acts alleged herein.

696. Defendant retaliated against Jeff Campie for opposing and refusing to participate in defendant's violations of state and federal statute and/or rules and regulations. In contesting defendant's violations, plaintiff was engaged in protected activity. Under Cal.

Lab. Code §1102.5 Defendant is prohibited from retaliation against plaintiff for opposing any practices forbidden or made unlawful under Cal. Lab. Code §1102.5.

697. Because Jeff Campie contested Defendant's violations of federal law, refused to accede to Defendant's practice of masking said violations, and took a position adverse to Defendant on the issue of covering up said violations, Defendant retaliated against Mr. Campie by wrongfully terminating him.

698. As a direct and proximate result of the willful, knowing, and intentional conduct of Defendant, and the failure to act by Defendant, Plaintiff-Relator has suffered mental distress, anguish, and indignation. Plaintiff is thereby entitled to general and compensatory damages in an amount to be proven at trial.

699. The acts of Defendant, as alleged herein, were done with fraud, oppression and malice, with a conscious disregard for Plaintiff-Relator's rights. As such, punitive damages are warranted against Defendant in order to punish and make an example of their actions.

### **COUNT THIRTY ONE**

#### **Retaliation in Violation of Cal. Lab. Code § 98.6 (Plaintiff-Relator Jeff Campie against Defendant Gilead Sciences, Inc.)**

700. Plaintiff-Relator Jeff Campie incorporates the allegations contained herein and hereby realleges them as set forth fully above.

701. In violation of Cal. Lab. Code § 98.6, Defendant retaliated against Plaintiff-Relator Jeff Campie for having opposed, resisted, and complained of the acts alleged herein.

702. Within a short time after Plaintiff-Relator complained of Defendant violations of various state and federal laws and regulations, plaintiff was ignored by his direct supervisor,

1 treated with hostility, and then was abruptly terminated and walked out the door, with a  
2 false announcement issued by Defendant.

3 703. As a result of Defendant and each of their actions, Plaintiff-Relator sustained economic  
4 damages to be proven at trial. As a further result of Defendant's actions, Plaintiff-Relator  
5 suffered emotional distress, resulting in damages to be proven at trial.  
6

7 704. The conduct of Defendant and/or its agents/employees as described herein was malicious,  
8 and/or oppressive, and done with a willful and conscious disregard for Plaintiff-Relator's  
9 rights and for the deleterious consequences of Defendant's actions. Defendant and/or its  
10 agents/employees or supervisors authorized, condoned and ratified the unlawful conduct  
11 of the remaining Defendant. Consequently, Plaintiff-Relator is entitled to punitive  
12 damages against Defendant.  
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### 15 COUNT THIRTY TWO

#### 16 **Retaliation in Violation of the Fair Labor Standards Act, 29 U.S.C. § 215** 17 **(Plaintiff-Relator Jeff Campie against Defendant Gilead Sciences, Inc.)**

18 705. Plaintiff-Relator Jeff Campie incorporates the allegations contained herein and hereby  
19 realleges them as set forth fully above.  
20

21 706. In violation of the Fair Labor and Standards Act of 1939 ("FLSA"), 29 U.S.C. §  
22 215(a)(3), Defendant retaliated against Plaintiff-Relator in discharging him because he  
23 made the above-described complaints regarding Defendant's numerous violations of  
24 federal law and rules and regulations.  
25

26 707. In making the above-described internal complaints to defendant, Plaintiff-Relator was  
27 engaged in a protected activity under the FLSA. Mr. Campie complained about  
28

1 Defendants' violations of the FLSA, in addition to violations of the Food, Drug, and  
2 Cosmetic Act, requirements contained in 21 C.F.R. § 210-211 and the declaration of  
3 Helsinki. Defendant willfully continued to mask the FLSA violations after Mr. Campie  
4 appraised defendant of the extent of Defendant's non-compliant practices. Mr. Campie  
5 took an adverse position to his employer by consistently refusing to acquiesce to their  
6 efforts to mask these violations. Mr. Campie subsequently suffered an adverse  
7 employment action when he was terminated from his employment by Defendant in  
8 retaliation for making said complaints and refusing to accede to defendant's masking of  
9 their unlawful practices.

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12 708. As a result of defendant's and each of their actions, Plaintiff-Relator sustained economic  
13 damages to be proven at trial. As a further result of Defendant's actions, Plaintiff-Relator  
14 suffered emotional distress, resulting in damages to be proven at trial.

15  
16 709. The conduct of Defendant and/or its agents/employees as described herein was malicious,  
17 and/or oppressive, and done with a willful and conscious disregard for Plaintiff-Relator's  
18 rights and for the deleterious consequences of Defendant's actions. Defendant and/or its  
19 agents/employees or supervisors authorized, condoned and ratified the unlawful conduct  
20 of the remaining Defendant. Consequently, Plaintiff-Relator is entitled to punitive  
21 damages against Defendant.

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24 **PRAYER FOR RELIEF**

25  
26 710. WHEREFORE, Plaintiffs/Relators Jeff and Sherilyn Campie, on behalf of themselves,  
27 the United States, and all states and cities listed herein, pray:  
28

- 1 711. Judgment in an amount equal to threefold the damages to be proven at trial against  
2 Defendants and in favor of the United States, plus a civil penalty of up to \$11,000 for  
3 each violation of 31 U.S.C. §3729;  
4
- 5 712. Judgment in an amount equal to threefold the damages to be proven at trial against  
6 Defendants and in favor of the State of California, plus a civil penalty of up to \$10,000  
7 for each violation of Cal. Govt. Code § 12651(a);  
8
- 9 713. Judgment in an amount equal to threefold the damages to be proven at trial against  
10 Defendants and in favor of the State of Delaware, plus a civil penalty of up to \$11,000 for  
11 each violation of 6 Del. C. § 1201 (a);  
12
- 13 714. Judgment in an amount equal to threefold the damages to be proven at trial against  
14 Defendants and in favor of the State of Florida, plus a civil penalty of up to \$10,000 for  
15 each violation of Fla. Stat. Ann. §68.082(2);  
16
- 17 715. Judgment in an amount equal to threefold the damages to be proven at trial against  
18 Defendants and in favor of the State of Georgia, plus a civil penalty of up to \$11,000 for  
19 each violation of Ga. Code Ann. §49-4-1 68.1 (a);  
20
- 21 716. Judgment in an amount equal to threefold the damages to be proven at trial against  
22 Defendants and in favor of the State of Hawaii, plus a civil penalty of up to \$10,000 for  
23 each violation of Haw. Rev. Stat. §661-21(a);  
24
- 25 717. Judgment in an amount equal to threefold the damages to be proven at trial against  
26 Defendants and in favor of the State of Illinois, plus a civil penalty of up to \$10,000 for  
27 each violation of 740 Ill. Comp. Stat. §1 75/3(a);  
28

- 1 718. Judgment in an amount equal to threefold the damages to be proven at trial against  
2 Defendants and in favor of the State of Indiana, plus a civil penalty of up to \$5,000 for  
3 each violation of IC 5-11-5.5-2(b);  
4
- 5 719. Judgment in an amount equal to the damages to be proven at trial against Defendants and  
6 in favor of the State of Louisiana, plus a civil fine in the amount of three times the  
7 amount of action damages sustained for each violation of La. Rev. Stat. § 437;  
8
- 9 720. Judgment in an amount equal to threefold the damages to be proven at trial against  
10 Defendants and in favor of the State of Massachusetts, plus a civil penalty of up to  
11 \$10,000 for each violation of Mass. Gen. L. Ch. 12 § 5B;  
12
- 13 721. Judgment in an amount equal to threefold the damages to be proven at trial against  
14 Defendants and in favor of the State of Michigan, plus a civil penalty of up to \$10,000 for  
15 each violation of MI Public Act 337;  
16
- 17 722. Judgment in an amount equal to threefold the damages to be proven at trial against  
18 Defendants and in favor of the State of Montana, plus a civil penalty of up to \$10,000 for  
19 each violation of Mont. Stat. Ann. 17-8-401;  
20
- 21 723. Judgment in an amount equal to threefold the damages to be proven at trial against  
22 Defendants and in favor of the State of New York, plus a civil penalty of up to \$10,000  
23 for each violation of N.Y. State Fin. §187 et seq.;  
24
- 25 724. Judgment in an amount equal to threefold the damages to be proven at trial against  
26 Defendants and in favor of the State of Nevada, plus a civil penalty of up to \$10,000 for  
27 each violation of Nev. Rev. Stat. Ann. §357.040(1);  
28

- 1 725. Judgment in an amount equal to threefold the damages to be proven at trial against  
2 Defendants and in favor of the State of New Hampshire, plus a civil penalty of up to  
3 \$10,000 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I);  
4
- 5 726. Judgment in an amount equal to threefold the damages to be proven at trial against  
6 Defendants and in favor of the State of New Jersey, plus civil penalties for each violation  
7 of N.J. Stat. 2A:32C-1 et seq.;  
8
- 9 727. Judgment in an amount equal to threefold the damages to be proven at trial against  
10 Defendants and in favor of the State of New Mexico, plus a civil penalty for each  
11 violation of N.M. Stat. Ann. §27-2F-4;  
12
- 13 728. Judgment in an amount equal to threefold the damages to be proven at trial against  
14 Defendants and in favor of the State of Oklahoma, plus a civil penalty of up to \$10,000  
15 for each violation of Okla. Stat. tit. 63 §5053.1(B);  
16
- 17 729. Judgment in an amount equal to threefold the damages to be proven at trial against  
18 Defendants and in favor of the State of Rhode Island, plus a civil penalty of up to  
19 \$10,000 for each violation of R.I. Gen Laws § 9-1.1-3 et seq.;  
20
- 21 730. Judgment in an amount equal to threefold the damages to be proven at trial against  
22 Defendants and in favor of the State of Tennessee, plus a civil penalty of up to \$10,000  
23 for each violation of Tenn. Code Ann. §54-18-103(a) and 71-5-182;  
24
- 25 731. Judgment in an amount equal to threefold the damages to be proven at trial against  
26 Defendants and in favor of the State of Virginia, plus a civil penalty of up to \$10,000 for  
27 each violation of Va. Code Ann. §8.01-216.3;  
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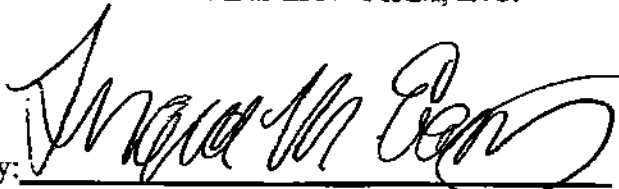
- 1 732. Judgment in an amount equal to threefold the damages to be proven at trial against  
2 Defendants and in favor of the State of Wisconsin, plus a civil penalty of up to \$10,000  
3 for each violation of Wis. Stat. § 20.931, et seq.;
- 4 733. Judgment in an amount equal to threefold the damages to be proven at trial against  
5 Defendants and in favor of the City of New York, plus a civil penalty of up to \$15,000  
6 for each violation of NYC Municipal Code, tit. 7, ch. 8 §§ 7-801 et seq.;
- 7 734. Judgment in an amount equal to threefold the damages to be proven at trial against  
8 Defendants and in favor of the City of Chicago, plus a civil penalty of up to \$10,000 for  
9 each violation of Chicago Mun. Code ch. 1-22-020;
- 10 735. Judgment in an amount equal to threefold the damages to be proven at trial against  
11 Defendants and in favor of the District of Columbia, plus a civil penalty of up to \$10,000  
12 for each violation of D.C. Code Ann. §2-308.14;
- 13 736. An award to the Plaintiff-Relators of the maximum amount allowed pursuant to  
14 §3730(d) of the False Claims Act, and the equivalent provisions of the state statutes and  
15 municipal ordinances set forth above;
- 16 737. That each and every Defendant be held jointly and severally liable for all damages and  
17 civil penalties described herein;
- 18 738. That the Plaintiff-Relators, the United States, and all States and cities listed herein be  
19 awarded all reasonable attorney fees and costs incurred, including expert witness fees;
- 20 739. That the Plaintiff-Relators, the United States, and all States and cities listed herein be  
21 awarded pre-judgment interest;
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- 1 740. That the Plaintiff-Relators, the United States, and all States and cities listed herein be  
2 awarded post-judgment interest;
- 3 741. That the Plaintiff-Relators be awarded all general damages, including but not limited to,  
4 pain and suffering;
- 5  
6 742. That the Plaintiff-Relators be awarded all double, treble, exemplary, and/or punitive  
7 damages and penalties, including but not limited to, penalties under any and all of the  
8 false claim statutes set forth herein, the California Labor Code, and the Fair Labor and  
9 Standards Act;
- 10  
11 743. That the Plaintiff-Relators be awarded equitable relief, including but not limited to  
12 reinstatement and the payment of lost wages and benefits and liquidated damages, plus  
13 interest pursuant to California Labor Code § 98.6 and 29 U.S.C. § 216(b);
- 14  
15 744. That the Plaintiff-Relators be awarded all special damages, including, but not limited to,  
16 compensation for compensatory damages;
- 17  
18 745. That defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the  
19 counterpart provisions of the state statutes and city ordinances set forth above, and that  
20 the Plaintiff-Relators be granted any and all preliminary and permanent injunctive relief,  
21 as appropriate;
- 22  
23 746. That the Plaintiff-Relators be granted any and all other relief set forth in the False Claims  
24 Act and the counterpart provisions of the state statutes and city ordinances set forth above  
25 which was not specifically referenced above;
- 26  
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1 747. That the Plaintiff-Relators be granted all other relief as may be appropriate.

2 Dated: January 30, 2014

3 EVANS LAW FIRM, INC.

4  
5 By: 

6 INGRID M. EVANS

7 Attorney for Plaintiffs

8 On behalf of Plaintiffs/Relators

9 Jeff Campie and Sherilyn Campie

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EVANS LAW FIRM, INC.